#### REMARKS

Entry of the foregoing and reconsideration of the above-identified application are respectfully requested. By the present Amendment, dependent Claim 52 has been replaced with new Claim 65, which merely independently recites the properties of the yeast expression vehicle recited in Claim 47, from which Claim 52 depended. In addition, the dependency of Claim 58 has been changed such that it refers to Claim 65 rather than canceled Claim 52. No new matter has been added.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing pending claims in condition for allowance. It is respectfully submitted that the proposed amendments replacing Claim 52 with new Claim 65 and the corresponding change in dependency of Claim 58 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Finally, it is respectfully submitted that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

Because the only remaining rejections relate to interference estoppel based upon Interference 102,728, Applicants take the opportunity to summarize the present claims and their relation to the Count in the interference. Specifically, the Count in the interference read as follows:

A DNA construct comprising a sequence of the following formula: 5'-L-S-Gene\*-3', where:

L encodes a Saccharomyces alpha-factor leader sequence recognized by a yeast host for secretion:

S encodes a spacer sequence providing processing signals resulting in the enzymatic processing by said yeast host of a precursor polypeptide encoded by L-S-Gene\* into the polypeptide encoded by Gene\*, S containing the sequence 5'-R<sub>1</sub>-R<sub>2</sub>-3' immediately adjacent to the sequence Gene\*, R<sub>1</sub> being a codon for lysine or arginine, R<sub>2</sub> being codon for arginine, with the proviso that S not contain the sequence 5'-R<sub>3</sub>-R<sub>4</sub>-X-3', where R<sub>3</sub>=R<sub>1</sub>, R<sub>4</sub>=R<sub>2</sub>, and X encodes a processing signal for dipeptidylaminopeptidase A; and Gene\* encodes a polypeptide foreign to Saccharomyces.

In summary, the subject matter of the Count in Interference 102,768 was a DNA construct which could express a foreign protein in yeast, wherein the foreign protein does not have any Glu-Ala sequences at the N-terminus. In contrast, the present claims are generic to DNA constructs which can express a foreign protein in yeast, regardless of whether the foreign protein contains Gly-Ala sequences at the N-terminus. The present claims also recite specific proteins which may be expressed, which the Count of Interference 102,768 did not.

The invention of the Count of Interference 102,768 was actually reduced to practice by Singh as a plasmid termed "p76". p76 was created by altering a construct which is a reduction to practice of the present claims, namely p60, which produced a protein containing the Glu-Ala sequences (see, e.g., Appendix E to the Amendment dated June 8, 2004).

The Federal Circuit has stated as a fact in the interference decision that p60, a construct within the scope of the present claims, was actually reduced to practice on October 1, 1982, i.e., well before the January 12, 1983 filing date of Brake's U.S. Patent No. 4,870,008 (the Brake '008 patent") in Interference 102,768 - the only date upon which Brake relied in that interference.

The following is a statement of the facts as set forth in our earlier opinion in this case. *Singh v. Brake*, 222 F.3d 1362, 55 USPQ2d 1673 (Fed. Cir. 2000). As we noted in that opinion, the factual context of Singh's alleged conception of the claimed DNA construct is based on his statements to the PTO and other record evidence. Absent qualification, the facts set forth here are not disputed by the parties.

In the course of Singh's attempts to design the claimed DNA construct in August 1982, he prepared plasmid p57, a circular DNA molecule containing the alpha-factor leader sequence and a spacer sequence directly adjacent to it. See Singh Decl. ¶ 21. During that same month, Singh incorporated the gene for human protein interferon D ("IFN-D") into p57, thereby yielding plasmid p58. See id. In p58, the gene was also positioned adjacent to the spacer sequence, such that the leader, spacer, and gene sequences were all oriented in a fashion

identical to the claimed construct. From September 6 to 11, 1982, Singh's assistant, Dr. June Lugovoy, isolated the DNA segment from p58 containing the alpha-factor leader, spacer, and IFN-D sequence, and inserted that segment (hereinafter "the p60 DNA construct") into yeast plasmid YEp9PT ("p60"). See id. ¶ 26. Plasmid p60 was then introduced into yeast cells to determine whether the p60 DNA construct would generate IFN-D. See id. ¶ 27.

On October 1, 1982, protein sequencing chemist Bill Kohr informed Singh that the IFN-D expressed by yeast cells transformed with p60 contained eight additional amino acids not normally present in natural IFN-D. See id. ¶ 33.

65 USPQ2d 1641, 1643 (Fed. Cir. 2003) (Emphasis added.) The Patent Office in considering this same issue determined by the Federal Circuit, must likewise adopt the findings determined by the appeals court, unless those findings have been undermined by new evidence. Fritsch v. Lin, 21 USPQ2d 1731 (Bd. pat. App. & Int. 1991). In the present case, there are no such undermining findings, and as such, the Patent Office must agree that Singh reduced to practice the generic invention of the present claims prior to Brake, and as such, there can be no estoppel.

The Examiner has rejected the present claims under 35 U.S.C. §102(g) as being unpatentable over the Count in Interference 102,728. This rejection is respectfully traversed.

The determination of who was the first to invent the subject matter of the present claims under 35 U.S.C. §102(g) was not the subject of the Interference 102,768. Indeed, if it had been, then as decided by the Federal Circuit in the above-noted quote, Singh would indeed have won the interference because Singh reduced to practice the invention of the present claims (e.g., p60) no later than October 1, 1982, two and a half months before Brake's filing date. As such, a rejection of the present claims over the Interference Count under 35 U.S.C. §102(g) is untenable and should be withdrawn. The rejection under 35 U.S.C. §103(a) is likewise untenable.

The question of who was the first to invent the subject matter of the present claims could not have been raised in Interference 102,768, because such generic claims were not

present in either Brake's '008 patent (Appendix A hereto) or in Singh's claims which existed at the time of the interference (in U.S. Application Serial No. 07/552,719), namely Claims 8 and 19-21, which read as follows:

- 8. A yeast expression vehicle comprising the DNA sequence encoding a lys arg C-terminal prepro peptide of yeast alpha factor gene operably connected in translation reading frame without intervening Glu (or Asp)-Ala dipeptide repeats to a DNA sequence encoding a mature protein heterologous to the yeast organism, wherein the DNA encoding all the Glu (or Asp)-Ala dipeptide repeats has been deleted from the prepro peptide of the yeast alpha factor DNA.
- 19. A process for obtaining a mature protein heterologous to yeast as a product of yeast expression, which process comprises:
- (a) transforming a yeast organism with an expression vehicle comprising the DNA sequence encoding a lys arg C-terminal pre-pro peptide of yeast alpha factor operably connected in translation reading frame without intervening Glu (or Asp)-Ala dipeptide repeats to a DNA sequence encoding a mature protein heterologous to the yeast organism, wherein the DNA encoding all of the Glu (or Asp)-Ala dipeptide repeats has been deleted from the pre-pro peptide of the yeast alpha factor DNA;
- (b) culturing the transformed organism; and
- (c) recovering mature protein from the culture having an N-terminal amino acid sequence identical to that of the protein from natural sources.
- 20. The yeast expression vehicle of claim 8 wherein the mature protein is human interferon-alpha-1.
- 21. The process of claim 19 wherein the mature protein is human interferon-alpha-1.

(Emphasis added.)

Because no such claims existed, Singh could not even have moved to add such claims to its application in interference. A party cannot seek to add a claim to an application in interference and request that it be designated as not corresponding to the Count. *L'Esperance v. Nishimoto*, 18 USPQ2d 1534 (Bd. Pat. App. & Int. 1991).

Likewise, Singh could not have requested that there be a second Count, because

Brake had no such corresponding generic claims in its '008 patent with which to interfere. In support of the rejection, the Examiner states "[n]otwithstanding the two-way obviousness test, the issue of priority of invention with respect to the more generic invention, that is, expression of mature and immature proteins, defined by the instant claims, is an issue that could have been raised and decided in an additional interference if Applicant had filed the proper preliminary motions during Interference 102,728, that is, an additional count for the interference representing the generic invention." The Examiner's statement is incorrect.

Party Brake had only a granted patent involved in the Brake v. Singh interference as declared in 1991. Since it is not possible to add claims to an issued patent, party Singh had no way to force party Brake to add claims to the generic invention and create an interference-in-fact with respect to that subject matter during the preliminary motions period of the Singh v.

Brake interference.

Facts quite similar to the present situation have indeed occurred, and the Board of Patent Appeals and Interferences has decided that loss of a species count does not create a *per se* rule of unpatentability for generic claims. In *Ex parte Hardman*, 142 USPQ 329 (Bd. Pat. App. & Int. 1964; a copy of which is provided herewith) the losing party in an interference with a species count submitted an affidavit under Rule 204, in the nature of an affidavit under Rule 131 (which was consistent with testimony in the interference) which showed that he conceived and reduced to practice the generic invention prior to the effective date of the patent, "by virtue of having made prior to said date various species falling under the claimed genus..." *Id.* at 330. In fact, the Board considered a finding to the contrary unjust:

We do not consider [the Examiner's conclusion] to be a just and equitable conclusion. Particularly in a situation where the interference is with a patent, an applicant copying all the claims from the patent which he can make, and as he must (Rule 205(a)), and involving both generic and species claims, priority as to the generic invention by applicant is not necessarily

disproved by his not being the first inventor of one species, which species is specifically claimed by the patentee, when it has been fully established that applicant in fact was the first to possess the generic aspects of the invention. In re Saunders, 1955, 104 USPQ 394. There is no indication of record that either of the two species was invented by the other party prior to the time that appellant made any one of the other species, or prior to the time that it may be considered appellant made the generic invention.

*Id.* Likewise here, there is no evidence that Brake invented the species of the count prior to the time Singh made the generic invention, because Brake chose rather to rely on its constructive reduction to practice in its January 12, 1983 application.

Indeed, in the comments to proposed Rule 41.207(b), it is acknowledged that the *Hardman* case was correct that there is no *per se* rule of unpatentability for generic claims after a party loses a species count. 69 Fed. Reg. 155 (August 12, 2004), a copy of which is submitted herewith. This is reiterated in the Manual of Patent Examining Procedure (MPEP) at 2138.01 IV, which specifically explains to Examiners that the loss of an interference count alone does not make its subject matter statutory prior art against the losing party.

In the present application, there has been a determination by the Federal Circuit, that Singh reduced to practice the generic invention of the present claims (e.g., p60) no later than October 1, 1982, and that "[a]bsent qualification, the facts set forth here are not disputed by the parties." As such, Singh is entitled to claims to the generic invention of the present claims, because Singh reduced to practice the invention of the present claims more than two months before Brake arguably constructively reduced to practice the species invention of Interference 102,768. Withdrawal of the rejections is therefore respectfully requested.

It is respectfully submitted that all rejections have been overcome by the above remarks. Thus, a Notice of Allowance is respectfully requested.

Attorney's Docket No. 704630-2001 Application No. 08/448,946 Page 11

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (202) 778-6150 so that prosecution of the application may be expedited.

> Respectfully submitted, BINGHAM MCCUTCHEN, L.L.P.

Date: 12/7/05

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#### Singh v. Brake

#### U.S. Court of Appeals Federal Circuit

No. 01-1621

Decided January 29, 2003

(Nonprecedential Opinion Issued October 16, 2002)

#### **PATENTS**

[1] Practice and procedure in Patent and Trademark Office — Interference — Rules and rules practice (§ 110.1704)

Practice and procedure in Patent and Trademark Office — Interference — Pleadings and submissions (§ 110.1706)

Board of Patent Appeals and Interferences did not abuse its discretion by returning junior party's brief, without further consideration, on ground that brief presented new arguments in derogation of board's reminder that only issues properly raised in earlier proceeding were entitled to review at final hearing, since junior party could have raised arguments in question at outset of interference, and to extent he did not do so, those arguments were waived, and since board's refusal to consider untimely arguments is not abuse of its discretion.

# [2] Patentability/Validity — Date of invention — Conception (§ 115.0403)

Substantial evidence support's finding by Board of Patent Appeals and Interferences that entries in laboratory notebook fail to corroborate junior party inventor's claim to prior conception of DNA construct that is subject of interference count, since there is nothing in notebook to corroborate inventor's testimony that three entries in question were meant to be read together, since notebook entries, at most, state goal that inventor hoped to achieve, but they do not provide any protocol or outline for loop deletion mutagenesis procedure necessary to obtain claimed construct, and since there is no evidence to support inventor's assertion that loop deletion mutagenesis had been developed before his claimed date of conception, or that he knew of such developments prior to senior party's filing date.

[3] Practice and procedure in Patent and Trademark Office — Prosecution — Filing date (§ 110.0906)

# Patentability/Validity — Specification — Written description (§ 115.1103)

Board of Patent Appeals and Interferences did not err in concluding that written description in senior party's earlier-filed application supports claim for DNA construct corresponding to interference count, since record does not support junior party's contention that specification in earlier application disclosed genus encompassing over 9000 species, of which count is directed to only two, or that specification failed to provide adequate direction to those of ordinary skill in art to lead them to subgenus of count, and since deference afforded board's conclusion under "substantial evidence" standard of review warrants finding of no legal error.

# [4] Patentability/Validity — Date of invention — Conception (§ 115.0403)

## Patentability/Validity — Specification — Enablement (§ 115.1105)

Finding by Board of Patent Appeals and Interferences that methods for obtaining DNA construct of interference count were available to those of ordinary skill in art as of filing date of senior party's earlier-filed application does not conflict with its conclusion that junior party inventor failed to establish prior conception of invention of count, since test for determining whether junior party conceived construct of count depends on his own personal knowledge of methods for making construct, and his formulation of definite and permanent idea for doing so, whereas test for whether senior party's application provided enabling disclosure does not depend on what senior party knew, but on whether application would have enabled one skilled in art to make and use invention at time application was filed.

## Particular patents — Chemical — DNA constructs

4,870,008, Brake, secretory expression in eukaryotes, judgment awarding inventor priority of invention, with respect to all claims of patent, in interference no. 102,728 affirmed.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent interference proceeding no. 102,728 between Arjun Singh, junior party (application serial no. 07/552,719), and Anthony J. Brake (patent no. 4,870,008), senior party. Junior party appealed from judgment awarding priority of invention to senior party, which was reversed and remanded (55 USPQ2d 1673). On remand, board again awarded judgment to senior party, from which junior party now appeals. Affirmed.

Prior decision: 55 USPQ2d 1673.

Sharon E. Crane, R. Danny Huntington, Bruce T. Wieder, and Donna M. Meuth, of Burns, Doane, Swecker & Mathis, Alexandria, Va., for appellant.

Debra A. Shetka and Thomas E. Ciotti, of Morrison & Foerster, Palo Alto, Calif.; Rachel Krevans and Jill Neiman, of Morrison & Foerster, San Francisco, Calif.; Robert P. Blackburn and Joseph H. Guth, of Chiron Corp., Emeryville, Calif., for appellee.

Before Lourie, circuit judge, Friedman, senior circuit judge, and Prost, circuit judge.

#### Lourie, J.

Arjun Singh appeals from the remand decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences awarding judgment in an interference to Anthony Brake. Brake v. Singh, Inter. No. 102,728, Paper No. 199 (Bd. Pat. App. & Inter. June 19, 2001). Because the Board's decision was supported by substantial evidence and was not contrary to law, we affirm.

#### BACKGROUND

This case arises out of an interference declared on November 12, 1991, involving a count corresponding to all thirty-seven claims of Brake's U.S. Patent 4,870,008 (hereinafter "the Brake patent") and claims 8 and 19-21 of Singh's U.S. Application 07/552,719.

The Brake patent issued from U.S. Application 07/081,302, filed August 3, 1987, which was a continuation of, and was accorded the benefit of, U.S. Application 06/522,909 (hereinafter "Brake 2"), filed August 12, 1983, assigned to Chiron Corporation. Singh's Application 07/552,719 was filed July 16, 1990, and was accorded the benefit of U.S. Application 06/506,098 (hereinafter "the Singh application"), filed June 20, 1983, and U.S. Applica-

tion 06/488,323, filed April 25, 1983, both assigned to Genentech, Inc.

Because the earlier Singh application predated Brake 2, Singh was initially designated the senior party in the interference. However, Brake 2 was a continuation-in-part of U.S. Application 06/457,325 (hereinafter "Brake 1"), filed January 12, 1983, and Brake successfully moved for the benefit of the filing date of Brake 1 with respect to the count in the interference. Brake also successfully moved to attack the benefit accorded Singh of the April 25, 1983 filing date of U.S. Application 06/488,323. Brake was then designated as the senior party.

The count, which is identical to claim 1 of Brake 2, reads as follows:

1. A DNA construct comprising a sequence of the following formula:

5'-L-S-Gene\*-3',

where:

L encodes a Saccharomyces alphafactor leader sequence recognized by a yeast host for secretion;

S encodes a spacer sequence providing processing signals resulting in the enzymatic processing by said yeast host of a precursor polypeptide encoded by L-S-Gene\* into the polypeptide encoded by Gene\*, S containing the sequence 5'- $R_1$ - $R_2$ -3' immediately adjacent to the sequence Gene\*,  $R_1$  being a codon for lysine or arginine,  $R_2$  being codon for arginine, with the proviso that S not contain the sequence 5'- $R_3$ - $R_4$ -X-3', where  $R_3$ = $R_1$ ,  $R_4$ = $R_2$ ,

and X encodes a processing signal for dipeptidylaminopeptidase A; and Gene\* encodes a polypeptide foreign to Saccharomyces.

Brake, Paper No. 199 at 6.

The DNA construct of the count thus includes three basic components: (1) a segment, "L," which encodes an alpha-factor leader sequence; (2) a segment, "S," which includes

Alpha-factor, also known as alpha-mating factor, is a peptide released by the budding yeast Saccharomyces, cerevisiae when a haploid cell is prepared to mate. See Bruce Alberts et al., Molecular Biology of the Cell 722 (3d ed. 1994). The yeast cell exports alpha-factor by way of a "leader sequence," which is attached to alpha-factor.

7. 7. 1. a first codon,<sup>2</sup> R<sub>1</sub>, encoding either lysine or arginine, followed by a second codon, R<sub>2</sub>, encoding arginine; and (3) a gene, "Gene\*," which encodes a protein of interest, in particular, a polypeptide foreign to (*i.e.*, not naturally produced by) the yeast Saccharomyces. See Brake patent, col. 2, ll. 11-16, 38-43.

After the DNA construct has been introduced into the yeast cell, e.g., via a plasmid vector, the cell "expresses" the construct, producing a polypeptide having the sequence of amino acids encoded by the DNA. The sequence of the resulting polypeptide, like the DNA encoding it, is divided into three regions: the alpha-factor leader, the spacer sequence including either a lysine-arginine or an arginine-arginine two-amino acid block, and the amino acid sequence of the protein of interest ("gene product").

According to the record in this case, the leader sequence functions to target the polypeptide for secretion from the yeast cell. During secretion, the yeast enzyme KEX-2 recognizes the lysine-arginine or arginine-arginine spacer sequence in the polypeptide and cleaves the polypeptide at the junction between the spacer and the gene product. As a result, the desired gene product is released into the extracellular medium, free of the leader and spacer portions of the polypeptide. See Brake, Paper No. 164 at 2. Because the yeast cell exports rather than retains the desired protein, protein purification is considerably simplified. See id.

The following is a statement of the facts as set forth in our earlier opinion in this case. Singh v. Brake, 222 F.3d 1362, 55 USPQ2d 1673 (Fed. Cir. 2000). As we noted in that opinion, the factual context of Singh's alleged conception of the claimed DNA construct is based on his statements to the PTO and other record evidence. Absent qualification, the facts set forth here are not disputed by the parties.

In the course of Singh's attempts to design the claimed DNA construct in August 1982, he prepared plasmid p57, a circular

DNA molecule containing the alpha-factor leader sequence and a spacer sequence directly adjacent to it. See Singh Decl. ¶21. During that same month, Singh incorporated the gene for human protein interferon D ("IFN-D") into p57, thereby yielding plasmid p58. See id. In p58, the gene was also positioned adjacent to the spacer sequence, such that the leader, spacer, and gene sequences were all oriented in a fashion identical to the claimed construct. From September 6 to 11, 1982, Singh's assistant, Dr. June Lugovoy, isolated the DNA segment from p58 containing the alpha-factor leader, spacer, and IFN-D sequence, and inserted that segment (hereinafter "the p60 DNA construct") into yeast plasmid YEp9PT ("p60"). See id. ¶ 26. Plasmid p60 was then introduced into yeast cells to determine whether the p60 DNA construct would generate IFN-D. See id. ¶ 27.

On October 1, 1982, protein sequencing chemist Bill Kohr informed Singh that the IFN-D expressed by yeast cells transformed with p60 contained eight additional amino acids not normally present in natural IFN-D. See id. ¶ 33. On approximately that same date, Singh alleges that he conceived the claimed DNA construct, i.e., he devised a plan to redesign the p60 DNA construct in order to obtain the desired gene product, IFN-D, free of those additional amino acids. See id. ¶ 34. Specifically, Singh claims that he realized that he would need to remove eight unwanted codons (twenty-four nucleotides) from the p60 DNA construct, and that he planned to accomplish this deletion by use of a technique known as "loop deletion mutagenesis."

On November 24, 1982, Singh wrote a laboratory notebook entry setting forth the undesired eight codons in the p60 DNA construct, as well as the twelve nucleotides on either side of that eight codon segment (the "flanking sequences"). See Singh Decl. ¶ 45. On that date, Singh also ordered a linear, 24-nucleotide sequence (a "24-mer") that comprised the nucleotides of the flanking sequences.<sup>3</sup> This order was can-

factor and signals that the peptide is to be exported from the cell. See U.S. Application 06/506,098 at 3, II. 3-5. That sequence is typically removed from alphafactor upon secretion. See id. at 3, II. 1-3. It is the alpha-factor leader sequence alone that is incorporated into the claimed construct.

<sup>&</sup>lt;sup>2</sup> A "codon" is a set of three nucleotides that codes for a particular amino acid.

<sup>&</sup>lt;sup>3</sup> Actually, this statement is incorrect. The 24-mer sequence that Singh ordered on November 24, 1982, was not identical to the nucleotides of the flanking sequences, but instead included several "preferred codons."

celed on the same day, and a notation in Singh's laboratory notebook stated that Singh would perform the deletion experiment in a different way "without changing codons." Id. On December 1, 1982, Singh ordered another 24-mer for the deletion experiment. This 24-mer was precisely complementary to the flanking sequences set forth in the November 24 entry. See Singh Decl. ¶ 47. DNA chemist Peter Ng testified that he synthesized the 24-mer for Singh on December 20, 1982. See Ng Decl. ¶ 11; Ng Dep. at 36. Singh affixed the order into his notebook on December 21, 1982, with a notation "oligonucleotide for making in-frame deletion of alpha pro-IFN-D junction."4 Singh alleges that these facts corroborate his testimony that he conceived the claimed DNA construct before January 12, 1983, the filing date of Brake 1.

Id. at 1364-65, 55 USPQ2d at 1674-75 (footnote omitted).

At the final hearing on May 11, 1998, Singh sought: (1) to contest the interlocutory order granting Brake the benefit of Brake 1; (2) to prove Singh's conception of the invention of the count prior to Brake 1's January 12, 1983 filing date; and (3) to show diligence throughout the "critical period" from just prior to January 12, 1983, until actual reduction to practice. Singh was unsuccessful with respect to all three issues, and final judgment was issued in favor of Brake on August 31, 1998. Brake, Paper No. 164.

Singh appealed to this court, contesting Brake's entitlement to the benefit of Brake 1 and contesting the Board's finding that Singh had failed to prove conception prior to the Brake 1 filing date. We held that certain of the Board's key findings underlying its conclusion that Singh had failed to prove conception of the subject matter of the interference prior to the effective filing date of Brake were unsupported by substantial evidence, and we vacated and remanded. Singh, 222 F.3d at 1370, 55 USPQ2d at 1679. We also found that the Board did not address whether Brake 1 adequately described and enabled the disputed subject matter of the count under 35 U.S.C.

§ 112, ¶ 1, and we remanded for determination of those issues as well. *Id.* at 1371, 55 USPQ2d at 1679.

On remand, the Board permitted the parties to submit briefs on the remanded issues, but returned Singh's enablement and written description briefs (as well as Brake's corresponding reply briefs) with its opinion, stating that Singh had failed to comply with the requirements of 37 C.F.R. § 1.655(a) and (b) by presenting new arguments not raised in the original opposition.

In an eighty-nine-page opinion with an additional seventeen-page concurrence, Brake, Paper No. 199, the Board addressed each of the issues on remand and concluded: (1) that Brake 1 adequately described and enabled the invention of the count, and Brake was therefore entitled to the benefit of Brake 1's filing date; (2) that Singh had not met his burden of proving conception prior to the filing date of Brake 1; and (3) that even if it were assumed, arguendo, that Singh had conceived the invention prior to Brake's filing date, Singh had not met his burden of demonstrating diligence between conception and reduction to practice:

Singh now appeals again. We have jurisdiction pursuant to 35 U.S.C. § 141 and 28 U.S.C. § 1295(a)(4)(A) (2000).

#### DISCUSSION

#### A. Return of Briefs

Pursuant to our earlier decision's remand "for determination of those issues that were properly raised during the earlier proceedings," Singh, 222 F.3d at 1371, 55 USPO2d at 1679, the Board invited the parties to submit briefs on the issues of Singh's case for priority and Brake's sustenance of his burden of proof with respect to written description and enablement. Brake, Paper No. 199 at 12. After the parties submitted the invited briefs, the Board determined that Singh had presented new arguments in derogation of the Board's reminder that only issues that were properly raised in the original opposition were entitled to review at the final hearing. Id. at 13. In response, the Board returned all of the newly submitted briefs to the parties without further consideration, holding that the briefs contained, "almost exclusively, new arguments, and lack the showing that Preliminary Motion 2 [concerning the Brake patent's entitlement

<sup>&</sup>lt;sup>4</sup> This point is disputed. Singh has provided no corroboration of his assertion that this notation was actually made on December 21, 1982. Like the other pages of Singh's notebook, this page was not witnessed until 1986, and, even then, there is no proof that the notation existed at the time of the witnessing.

to the Brake 1 filing date] should be modified." *Id.* at 15.

[1] Singh argues that the Board erred in refusing to consider briefs submitted by Singh on remand. We review the Board's application of its rules for an abuse of discretion. Brown v. Barbacid, 276 F.3d 1327, 1332, 61 USPQ2d 1236, 1238 (Fed. Cir. 2002). Although returning the briefs to the parties is a rather extraordinary measure, we do not find any abuse of discretion in the Board's doing so. 37 C.F.R. § 1.655(b) states:

A party shall not be entitled to raise for consideration at final hearing any matter which properly could have been raised by a motion under § 1.633 or 1.634 unless the matter was properly raised in a motion that was timely filed by the party under § 1.633 or 1.634 and the motion was denied or deferred to final hearing, the matter was properly raised by the party in a timely filed opposition to a motion under § 1.633 or 1.634 and the motion was granted over the opposition or deferred to final hearing, or the party shows good cause why the issue was not properly raised by a timely filed motion or oppositions.

#### 37 C.F.R. § 1.655(b) (2002).

Because the Board found that Singh was attempting to raise in his briefs matters that could have been but were not raised at the outset of the interference, see Brake, Paper No. 199 at 12, the Board was acting properly within its discretion when it refused to consider the briefs. Singh could have raised his written description and enablement arguments at the outset of the interference; to the extent that he did not do so, those arguments have been waived. As we stated in Credle v. Bond, 25 F.3d 1566, 30 USPQ2d 1911 (Fed. Cir. 1994), the Board does not abuse its discretion when it declines to consider untimely arguments. Id. at 1572 n.14, 30 USPQ2d at 1916 n.14. Furthermore, because the Board explicitly stated in its November 2, 2000 order that additional briefing was optional, Brake, Paper No. 179 at 5, it is difficult to see how the subsequent refusal to consider the briefs could have been an abuse of discretion.

Singh also asserts that the Board refused to consider certain arguments made in his "original" Main Brief. We find no abuse of discretion. Again, Singh did not show good cause for failing to raise these arguments at

the preliminary motion stage, and the Board was entitled to decline to consider them.

## B. Conception and Reduction to Practice

"Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is therefore to be applied in practice." Kridl v. McCormick, 105 F.3d 1446, 1449, 41 USPQ2d 1686, 1689 (Fed. Cir. 1997) (citations omitted). A conception must encompass all limitations of the claimed invention, see id., and "is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation," Burroughs Wellcome Co. v. Barr Labs. Inc., 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994).

Priority of invention and its constituent issues of conception and reduction to practice are questions of law predicated on subsidiary factual findings. Brown, 276 F.3d at 1332, 61 USPQ2d at 1238; Hitzeman v. Rutter, 243 F.3d. 1345, 1353, 58 USPQ2d 1161, 1166 (Fed. Cir. 2001). Accordingly, we review de novo the Board's legal conclusions with respect to priority, conception, and reduction to practice, 5 U.S.C. § 706 (2000); Brown, 276 F.3d at 1332, 61 USPQ2d at 1238; Hitzeman, 243 F.3d at 1353-54, 58 USPQ2d at 1166-67. and we review factual findings by the Board for substantial evidence, Dickinson v. Zurko. 527 U.S. 150 [50 USPQ2d 1930] (1999); In re Gartside, 203 F.3d 1305, 1315, 53 USPO2d 1769, 1775 (Fed. Cir. 2000).

A junior party whose effective filing date is earlier than the date the senior party's patent issued and who is seeking a determination of priority must demonstrate by a preponderance of the evidence either reduction to practice before the senior party's priority date, or prior conception coupled with reasonable diligence in reducing the invention to practice from a time just prior to the senior party's entry into the field to the junior party's own reduction to practice. 35 U.S.C. § 102(g) (2000); Griffin v. Bertina, 285 F.3d 1029, 1032, 62 USPQ2d 1431, 1433 (Fed. Cir. 2002); Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1577, 38 USPQ2d 1288, 1290 (Fed. Cir. 1996).

It is well established that when a party seeks to prove conception via the oral testimony of a putative inventor, the party must

proffer evidence corroborating that testimony. See Mahurkar, 79 F.3d at 1577, 38 USPQ2d at 1290; Price v. Symsek, 988 F.2d 1187, 1194, 26 USPQ2d 1031, 1036 (Fed. Cir. 1993). That rule addresses the concern that a party claiming inventorship might be tempted to describe his actions in an unjustifiably self-serving manner in order to obtain a patent or to maintain an existing patent. See Eibel Process Co. v. Minn. & Ont. Paper Co., 261 U.S. 45, 60 (1923); Kridl, 105 F.3d at 1450, 41 USPQ2d at 1689 ("The tribunal must also bear in mind the purpose of corroboration, which is to prevent fraud, by providing independent confirmation of the inventor's testimony."); Price, 988 F.2d at 1194-95, 26 USPQ2d at 1036-37. There is no particular formula that an inventor must follow in providing corroboration of his testimony of conception. See Kridl, 105 F.3d at 1450, 41 USPQ2d at 1689. Rather, whether a putative inventor's testimony has been sufficiently corroborated is determined by a "rule of reason" analysis, in which "an evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached." Price, 988 F.2d at 1195, 26 USPQ2d 1031 at 1037. However, that "rule of reason" analysis does not alter the requirement of corroboration of an inventor's testimony. Brown, 276 F.3d at 1335. Evidence of the inventive facts must not rest alone on the testimony of the inventor himself. Cooper v. Goldfarb, 154 F.3d 1321, 1330, 47 USPQ2d 1896, 1903 (Fed. Cir. 1998).

Singh argues that the Board did not consider the totality of the corroborative evidence establishing Singh's conception, but only considered individual pieces of evidence in "total isolation from one another." Specifically, Singh argues that his November 24, 1982 notebook entry and his ordering of the specific 24-mer oligonucleotide ultimately used to carry out the loop deletion mutagenesis method (in February 1983) establish that he had a definite and permanent idea of the structure of a DNA construct within the count and of an operative way of making it prior to Brake 1's filing date.

We disagree. First, as we stated in our earlier opinion, Singh, 222 F.3d at 1368, 55 USPQ2d at 1677, the Board correctly held as a matter of law that Singh failed to prove that he conceived the claimed construct prior to December 1, 1982. In his November 24, 1982

notebook entry, Singh identified the twentyfour nucleotides encoding the eight extraneous amino acids present in the IFN-D generated by the p60 DNA construct, labeling them with the notation, "sequence to be removed." He also identified in that entry the twelve nucleotides immediately upstream and the twelve nucleotides immediately downstream from those twenty-four, i.e., the flanking segments. Accordingly, he may have articulated in that entry the problem to be solved, namely, the need to eliminate the twenty-four nucleotides encoding the extraneous amino acids. Nonetheless, substantial evidence supports the Board's finding that that entry alone was insufficient to corroborate Singh's testimony. Even if the entry expressed the problem, it did not provide the solution. See Brake, Paper No. 164 at 22-24. The Board's key findings in this regard, both of which are supported by substantial evidence in the notebook entry itself, are: (1) that a linear 24-mer other than the one necessary to accomplish the deletion was first ordered, and (2) that the order was canceled the same day, with a notation "will do in a different way and w/o changing codons." Id. at 23-24.

Secondly, as noted above, the 24-mer sequence that Singh initially ordered on November 24, 1982, was not identical to the nucleotides of the flanking sequences. Instead, he included several "preferred codons," casting doubt on the accuracy of Singh's statement that he ordered that 24-mer "[i]n order to remove this sequence by oligonucleotide deletion mutagenesis." While it remains unclear exactly what Singh "planned" to do on November 24, 1982, his identification of preferred codons suggests to us that his plans may not have included the use of loop deletion mutagenesis.

The Board duly considered the fact that the 24-mer ordered by Singh on December 1, 1982, was indeed complementary to the four codons on each side of the sequence Singh allegedly desired to delete. See, e.g., Brake, Paper No. 199 at 13-14, 19, 58-59, 77-78. The Board also reviewed Singh's notebook pages purporting to demonstrate conception. The Board concluded, and we agree, that "Singh's entire case for conception rests on the order of a 24-mer and an uncorroborated notation in a corner of Dr. Singh's notebook." Id. at 84.

[2] There is nothing in Singh's notebook that corroborates his testimony that the No-

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vember 24, December 1, and December 21 entries were meant to be read together. Even viewing all of these entries together, however, we find that the sum falls short of proving by a preponderance of the evidence that Singh had a definite and permanent idea of an operative method of making the DNA construct of the count prior to Brake 1's filing date. As the Board observed, the notebook entries do not provide any protocol or outline of the loop deletion mutagenesis procedure: "At best, the notation states a goal which Dr. Singh hopes to achieve; i.e., an in-frame deletion of the á pro-IFN-D junction." Id. at 61. Adelman et al., In Vitro Deletional Mutagenesis for Bacterial Production of the 20,000-Dalton Form of Human Pituitary Growth Hormone, 2 DNA 183 (1983), which described the loop deletion mutagenesis procedure, also described using oligonucleotides complementary to nucleotide sequences flanking codons to be deleted as probes for identifying plasmids from which the codons had been deleted. Id. at 188. We find it no less plausible that Singh was ordering the 24-mer for use as a probe than it was that he was ordering it for use in the loop deletion mutagenesis procedure. Indeed, Singh has pointed to no evidence in the record in support of his assertion that loop deletion mutagenesis was developed at Genentech in late 1982 (the Adelman et al. paper was published in 1983), let alone that Dr. Singh knew of any such developments prior to Brake 1's filing date. The burden was on Singh to prove that he as the inventor had a definite and permanent idea of how to make the construct. See Coleman v. Dines, 754 F.2d 353, 360, 224 USPQ 857, 863 (Fed. Cir. 1985). That he did not do.

Finally, we address Singh's argument set forth in his brief that, "[w]ith respect to the issue of conception, this Court previously made specific findings ... that Singh articulated a specific plan to design the claimed construct by the loop deletion method on November 24, 1982." That statement is a mischaracterization of our earlier opinion, in which we simply said that the Board needed to consider the totality of the evidence, including evidence of Singh's identification of the "sequence to be removed" and the twelve nucleotides immediately upstream and downstream from this sequence, as well as of his ordering of a 24-mer identical to the se-

quences flanking the undesired sequence. We are satisfied that the Board has done so.

Thus, after review of the record evidence in light of the proper legal standards, we conclude that substantial evidence supports the Board's key finding that no evidence links the nucleotide Singh ordered on December 1, 1982, with a plan to design the claimed construct prior to January 12, 1983.

Because we find that Singh did not meet his burden of demonstrating conception prior to Brake 1's filing date by a preponderance of the evidence, we need not address Singh's arguments regarding reduction to practice. However, we note the Board's finding that, apart from attorney argument, "Singh's evidence of diligence primarily consists of various pages from Dr. Singh's laboratory notebook which are (i) unexplained as to content and relevance to the invention of the Count, and (ii) uncorroborated." Brake, Paper No. 199 at 88. We agree that Singh's activities completed on December 20, 1982, were the only relevant, corroborated activities performed by Singh prior to Brake 1's January 12, 1983, filing date, and, as a result, Singh failed to prove reasonable diligence toward reduction to practice by a preponderance of the evidence.

## C. Written Description and Enablement

Whether a specification supports a claim corresponding to a count, and thus satisfies the written description requirement of 35 U.S.C. § 112, ¶ 1, is a question of fact, Vas-Cath v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991), and is, in appeals from the United States Patent and Trademark Office, reviewed under the substantial evidence standard. In re Gartside, 203 F.3d at 1315, 53 USPQ2d at 1775. Singh argues that the Board erred in concluding that Brake is entitled to the benefit of the Brake 1 application. First, Singh contends that Brake did not provide an adequate written description of the invention of the count in the Brake 1 application, and should not be entitled to its benefit. According to Singh, Brake 1 disclosed a large genus, allegedly encompassing over 9000 species<sup>5</sup> (n is 0 or 1 to 4), of which the count is directed to only two (i.e., those where n = 0).

<sup>&</sup>lt;sup>5</sup> Singh bases that number on the formula "((R), (GAXYCX), Gene\*)," disclosed at page 3, line 33, of Brake 1, in which R = CGX or AZZ; r = "an integer of from 2 to 4, . . . , preferably 2"; X = T, G, C, or A; Y =

Secondly, Singh asserts that Brake 1 does not provide an enabling disclosure with respect to the invention of the count, arguing that Brake 1 does not disclose how to make and use the "n = 0" embodiment, and that "the techniques which were available to Brake at the time of filing the Brake 1 Application were not sufficient to obtain the DNA constructs of the Count." Singh also argues that Brake 1 "is replete with passages which guide one of ordinary skill in the art to constructs wherein n > 0, which constructs are not encompassed by the Count." Finally, Singh argues that "during prosecution of the Brake 2 Application, Brake argued that the results obtained with the n = 0construct were unexpected, because those of ordinary skill in the art believed that the Glu-Ala sequences were required."

[3] Singh's arguments are not persuasive. First, we disagree with Singh's argument that the invention of the count represents just two of 9000+ species disclosed in Brake 1. Singh's calculation of 341 permutations for (GAXY-CX), is apparently based on an unwarranted assumption that each iteration of the parenthetical sequence is independently chosen. However, as Brake pointed out, because the variable 'n' is outside the parentheses, (GAXYCX), can code for either no amino acids (i.e., when n = 0), or 1 to 4 copies of one of four different amino acid sequences (i.e., Asp-Pro, Asp-Ala, Glu-Pro, or Glu-Ala). Brake, Paper No. 199 at 20-21 n.13. Thus, there are at most only seventeen (i.e.,  $4^0 + 4^1$  $+4^{1}+4^{1}+4^{1}$ ) permutations of that sequence. Even among those seventeen, however, we agree with Brake that there are only two meaningful embodiments: one in which a dipeptidylaminopeptidase A (DPAP) signal is present (i.e., n = 1 to 4), and one in which it is not (i.e., n = 0).

Moreover, Singh's calculation of twentyeight possibilities for the Lys/Arg sequences is artificially inflated because it ignores the disclosure of claim 5 of Brake 1:

5. A DNA construct comprising a sequence of the following formula:

L-(R-S-(GAXYCX)<sub>n</sub>-Gene\*)<sub>v</sub>

wherein:

L is a leader sequence recognized by yeast for secretion;

R and S are codons coding for arginine and lysine;

X is any nucleotide;

Y is guanosine or cytosine;

y is an integer of from about 1 to 10;

Gene\* is a gene foreign to yeast; and

n is 0 or 1 to 4.

U.S. Application 06/457,325 at 16, ll. 20-32.

In claim 5, spacer R-S encodes four possible sequences (i.e., Lys-Arg, Arg-Arg, Arg-Lys, or Lys-Lys), not 28. Of these four, two permutations, Lys-Arg and Arg-Arg, are within the scope of the count.

Singh cites Fujikawa v. Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996), for the proposition that an application disclosing a generic chemical formula must provide adequate direction to those of ordinary skill in the art to lead them to a subgenus of the proposed count. We find Singh's reliance on Fujikawa to be unsound. In Fujikawa, we held that disclosure of a generic quinoline structure with four variable groups, each of which could be independently chosen from a list of functional groups, provided insufficient written description support for a count directed to a subgeneric structure having a single combination of the four groups. Id. at 1569-71, 39 USPQ2d at 1904-05. However, Brake 1's formula does not present the same issue as did the quinoline in Fujikawa. First, replacing a functional group on a chemical compound can often have highly unpredictable results. We noted in Fujikawa that even a change as seemingly trivial as replacing an isopropyl group with the isosteric cyclopropyl group at issue in that case could result in either a significant improvement or reduction in the activity of the compound against a particular biological target. Id. In the present case, on the other hand, as mentioned above, there are only two subgenera that are biologically relevant: one in which a DPAP signal is present (i.e., n = 1

G or C; y = "an integer of least one and usually not more than 10, more usually not more than four ..."; Z = A or G; and n = "0 or an integer which will generally vary from 1 to 4, usually 2 to 3."

According to Singh, Each "R" can encode either Lys or Arg, so (R)r can encode twenty-eight (i.e., 2<sup>2</sup> + 2<sup>3</sup> + 2<sup>4</sup>) different amino acid sequences. In addition, each "GAXYCX" sequence can encode any of four amino acid sequences: Asp-Pro, Asp-Ala, Glu-Pro, or Glu-Ala, so (GAXYCX)<sub>n</sub> can encode 341 (i.e., 4<sup>0</sup> + 4<sup>1</sup> + 4<sup>2</sup> + 4<sup>3</sup> + 4<sup>4</sup>) different amino acid sequences. Thus, Singh argues that the Brake 1 formula covers 9548 (i.e., 28 x 341) different species.

to 4), and one in which it is not (i.e., n = 0), a simpler case than in Fujikawa. Here, moreover, claim 5 of Brake 1 discloses that "n is 0 or 1 to 4," which is a clear "blaze mark" providing in ipsis verbis support for "n = 0" in the count. In re Ruschig, 379 F.2d 990, 994-95, 154 USPQ 118, 122 (CCPA 1967).

The Supreme Court has explained that "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." In re Gartside, 203 F.3d at 1312, 53 USPO2d at 1773 (citing Consolo v. Federal Maritime Comm'n, 383 U.S. 607, 620 (1966)). In Fujikawa, we said that "[w]hile Fujikawa's arguments are not without merit, we cannot say, on this record, that the Board's decision was clearly erroneous." 93 F.3d at 1571, 39 USPQ2d at 1905. In view of the fact that the "substantial evidence" standard of review that we now use post-Zurko requires us to give decisions of the Board greater deference than we gave in cases such as Fujikawa, we likewise decline to find legal error in the Board's conclusion on the record in the present case.

Singh's reliance on Bigham v. Godtfredsen. 857 F.2d 1415, 8 USPQ2d 1266 (Fed. Cir. 1988), is also unavailing. In Bigham, Godtfredsen's first application disclosed a compound having a substituent "X", where X was defined as "a halogen atom." The application provided as its only example a compound in which X was chloro. Id. at 1416, 8 USPO2d at 1267. This court ruled that that application's disclosure of "halogen" did not meet the requirements of § 112 as a written description of bromo or iodo species, particularly where Godtfredsen had earlier argued in the same case that bromo and iodo were patentably distinct from chloro in order to urge bifurcation of the count. Id. at 1417, 8 USPO2d at 1268. In the present case, in contrast, "n = 0" was disclosed in Brake 1. If Godtfredsen had provided examples of fluoro, bromo, and iodo compounds in addition to the chloro compound, that case might have been decided differently, even in spite of Godtfredsen's "patentably distinct" argument.

Singh's arguments with respect to enablement are likewise unconvincing. Enablement is a question of law based on underlying factual determinations. *In re Swartz*, 232 F.3d 862, 863, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000). We review the Board's underlying

findings of fact for substantial evidence, and review de novo its ultimate conclusion whether a disclosure is enabling. Id. Singh argues in his brief:

The Board takes internally inconsistent positions with respect to whether methods for obtaining a construct of the Count using Brake's starting material were available to those of ordinary skill in the art at the time the Brake 1 Application was filed. To support its finding that Brake is entitled to benefit, the Board finds that such methods existed. However, to support its finding that Singh had not conceived of the invention prior to the Brake 1 Application filing date, the Board makes the contrary finding.

[4] We find no error or inconsistency in the Board's analysis. As we wrote in Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1050, 34 USPQ2d 1565, 1569 (Fed. Cir. 1995), "the enablement requirement ... looks to the objective knowledge of one of ordinary skill in the art." Id. (citing Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1532, 3 USPQ2d 1737, 1742 (Fed. Cir. 1987)). Thus, whereas the test for determining whether or not Singh conceived the construct of the count depended on Singh's own personal knowledge of methods for making the construct and his formulation of a definite and permanent idea therefor, whether Brake 1 enables an invention within the count does not depend on what Brake knew, but rather on whether the application enables one skilled in the art to make and use the invention, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), "at the time the patent application was filed." Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1345, 56 USPQ2d 1332, 1337 (Fed. Cir. 2000). The Board found that the testimony of Brake's witness, Dr. Patricia Tekamp-Olson, demonstrated that those of ordinary skill in the art had in their possession in 1982 various molecular biological methods sufficient to make and use the "n = 0" construct, including site-directed mutagenesis. Brake, Paper No. 199 at 24-27. The Board also found that Singh's expert, Dr. Joseph Falkinham, mischaracterized the teachings of the Fritz article on which he relied in his attempts to discredit Tekamp-Olson's testimony. Id. at 40.

As further "proof" that Brake 1 does not provide an enabling disclosure of the inven-

tion of the Count, Singh also alleges, for example, that "the Brake 1 Application actually steers the artisan to species clearly outside the Count," that "during prosecution of the Brake 2 Application, Brake argued that the results obtained with the n = 0 construct were unexpected," and that "Dr. Brake did not realize the disadvantages of the n > 0 constructs until well after the Brake 1 Application was filed." We are not persuaded by any of these arguments, and conclude that Singh has apparently confused the criteria for proving obviousness with those for demonstrating that a disclosure is nonenabling. Although the questions (1) whether or not a reference "teaches away" from a claimed invention and (2) whether or not a claimed invention provides "unexpected results" are relevant in determining whether or not a claimed invention would have been obvious, W.L. Gore & Assocs., Inc. v. Garlock. Inc., 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), they are not the primary questions bearing on enablement. The fact that the Brake patent states that n in the construct is "preferably 2 or 3" is also irrelevant to the question of enablement of the n = 0 construct.<sup>6</sup> Similarly, the fact that the n = 0 construct might have had after-discovered advantages over the n > 0 constructs has no bearing at all on whether or not Brake 1 contained an enabling disclosure.

We thus conclude that substantial evidence supports the Board's finding that Brake was entitled to the benefit of the Brake 1 application. We have considered Singh's other arguments and do not find them persuasive.

#### CONCLUSION

Because the Board's decision was supported by substantial evidence and contained no errors of law, the Board did not err in concluding that Singh failed to show (1) that Brake was not entitled to the Brake 1 filing

date and (2) that Singh reduced the invention to practice before Brake's priority date. The Board's decision to award judgment to Brake is therefore

AFFIRMED.

Time Warner Entertainment Co. v. Jones

U.S. Patent and Trademark Office Trademark Trial and Appeal Board

> Opposition No. 112,409 Decided July 17, 2002

# TRADEMARKS AND UNFAIR TRADE PRACTICES

[1] Practice and procedure in Patent and Trademark Office — Interpartes proceedings — Opposition and cancellation — Rules and rules practice (§ 325.0305.05)

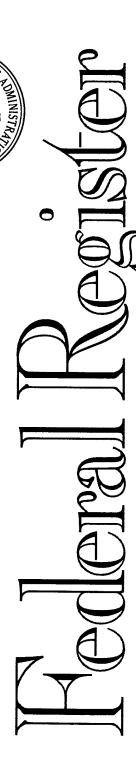
JUDICIAL PRACTICE AND PROCEDURE

Procedure — Evidence — In general (§ 410.3701)

Procedure — Discovery — Interrogatories (§ 410.4005)

Trademark applicant's objection to opposer's deposition testimony, on ground that opposer refused to "identify each and every fact, document and witness in support of its pleaded allegations" as requested in applicant's interrogatories, is overruled, since applicant's requests are equivalent to improper request for identification of fact witnesses and trial evidence prior to trial, since applicant has: not been deprived of opportunity for discovery, or subjected to "trial by ambush," and since applicant did not formally or clearly: raise objection until she filed her brief, and therefore has waived her objection to opposit er's testimony deposition evidence and attached exhibits.

<sup>&</sup>lt;sup>6</sup> The Board properly discredited Falkinham's testimony on that point. Paragraph 9 of Falkinham's Declaration states: "Although there was a theoretical presentation of the n=0 construct in the Brake 1 application, there was a clear statement that 'n' in the construct was 'preferably 2 or 3' (column 3, line 25) or 'usually 2 or 3' (column 2, line 68) ... One skilled in the art would have determined from the Brake specification that the n=0 construct was not desirable." As the Board noted, Brake, Paper No. 199 at 36, Falkinham's citations to "columns" 2 and 3 obviously refer to the Brake patent (of which claim 1 is identical to the Count in this interference), and not to Brake 1.



Thursday, August 12, 2004

## Part II

# Department of Commerce

Patent and Control Office

37 CFR Parts 1, 5, 10, 11, and 41 Rules of Practice Before the Board of Patent Appeals and Interferences; Final Rule

§ 41.202(b) is too restrictive, while two of the comments suggest it might be inconsistent with the more restrictive § 1.99.

Answer: The rule is not intended to create, eliminate, or modify a remedy available under § 1.99 or § 1.291. The rule simply observes that the process for suggesting an interference is not available to a patentee and points to an alternative remedy. Section 41.202(b) is revised to clarify this intent and to point patentees to both § 1.99 and § 1.291.

Comment 168: One comment expresses concern about § 41.202(c), under which an examiner may require an applicant to add an interfering claim. The comment worries that the applicant is placed in an awkward position if an examiner suggests an interfering claim that the applicant believes is improper because it is not supported or because the examiner's reasoning is unclear.

Answer: The applicant's remedy in such a situation is to comply with the requirement, but also to add a better claim or to contest the requirement. See In re Ogiue, 517 F.2d 1382, 1390, 186 USPQ 227, 235 (CCPA 1975) (holding that refusal to copy a claim for which the applicant had support results in disclaimer). The requirement that an applicant either comply by adding the proposed claim or concede priority of the proposed subject matter is not new, see 37 CFR 1.605 (2003) and MPEP § 2305. Section 41.202(c) has been further modified to require showings like those under  $\S 41.202(a)(2)-(a)(6)$ when the interference would be with a patent. Any dispute arising as to satisfaction of these added procedural requirements may be petitioned.

Comment 169: Three comments address the requirement under § 41.202(d) to show priority. Two of the comments suggest restoring some version of the reduced showing required under § 1.608(a) (2003) for an application with an effective filing date within three months of an interfering patent's effective filing date. A third comment suggests that a similar requirement be made of all junior patentees.

Answer: The three-month practice under § 1.608 (2003) was eliminated because it makes little sense in many circumstances. The comments assume that a fairly common practice prevails to spend a few months preparing applications. The argument fails for two reasons.

First, while it may be common generally, it does not appear to be common in all technologies and may be meaningless in the context of a particular case. Second, if we are to assume that the applicant spent three

months preparing an application, then we should also be able to make the same assumption about the earlier-filing interfering patent, in which case the assumption does little to address whether the applicant was the first to invent. See *Paulik v. Rizkalla*, 760 F.2d 1270, 1282, 226 USPQ 224, 232–33 (Fed. Cir. 1985) (Rich, J., concurring; making a similar point).

Comment 170: One comment suggests distinguishing between complex and simple technologies in § 41.202(d). The comment does not offer a definition of simple or complex technology.

Answer: Such a distinction would be unworkable in practice.

Comment 171: Another comment suggests waiting until the interference is initiated to require the showing under § 41.202(d).

Answer: A practice of waiting would require the declaration of an interference, with all of the costs associated with the declaration of an interference, that the applicant might not want to contest. Moreover, since an inadequate showing under § 41.202(d) is the trigger for a summary disposition under § 41.202(d)(2), delay in making the showing would drag out the pendency of the interference.

Comment 172: One comment suggests requiring a showing under § 41.202(d) from junior patentees as well.

Answer: In an interference, the Office does not have jurisdiction over the patent until after the interference is declared. Once the Board declares an interference, a junior party must make a priority statement under § 41.204(a). Normally, the priority statement is required early in the interference. Nothing in the rules prevents a summary proceeding for a patentee that cannot show an adequate date of priority in its priority statement. Moreover, nothing prevents the Board from expediting consideration of priority in such circumstances.

Section 41.202(e) addresses what evidence is sufficient to show priority. Paragraph (2) has been added to address a situation in which a showing cannot be made because the necessary evidence is not available without a subpoena. In such cases, a detailed proffer of the expected testimony or production may suffice.

Comment 173: Eight comments

Comment 173: Eight comments address § 41.203(a)'s definition for interfering subject matter. Seven oppose the rule, while one seeks clarification.

The seven that oppose would all prefer that the Board use a one-way test for interfering subject matter.

Answer: A one-way test is not workable since it would turn a large portion of rejections under 35 U.S.C.

102(a), 102(e), and 103(a) into interferences simply because the subject matter claimed in the prior art anticipated or rendered obvious the subject matter subsequently claimed.

The one-way practice has never been the standard for interfering subject matter. Although some comments suggest that the two-way test of § 41.203(a) originated with Winter v. Fujita, 53 USPQ2d 1234 (BPAI 1999), that decision only originated the use of the term "two-way" in the context of interfering subject matter. The two-way test itself has long been implicit in the test for no interference-in-fact: one-way patentable distinctness. See, e.g., Aelony v. Arni, 547 F.2d 566, 570, 192 USPQ 486, 490 (CCPA 1977). It is worth noting that the test for interfering patents under 35 U.S.C. 291 had been framed in, if anything, even narrower terms than the test under § 41.203(a). See e.g., Slip Track Sys. v. Metal Lite, Inc., 159 F.3d 1337, 1341, 48 USPQ2d 1055, 1058 (Fed. Cir. 1998) ("patents that claim identical subject matter").

Comment 174: One comment suggests that the paradox of having a one-way test for both starting and ending an interference could be resolved if the test for no interference-in-fact only worked in one direction. That is, the movant must show that its claim is patentably distinct from the opponent's claim rather than showing that the opponent's claim is patentably distinct from the movant's claim. The example given is a genus claim that is anticipated by, but does not anticipate, another party's species claim.

Answer: The problem with this suggestion is that it cedes control over the interference to the party with the species claim, who can decide unilaterally whether to file for no interference-in-fact or not. The suggested directional test also ignores the Director's role under 35 U.S.C. 135(a) in deciding whether an interference exists or not.

Under the directional test, an interference would both exist and not exist. If the Director turns a blind eye to the fact that there is no interference-infact from one perspective, the Director has effectively enlisted on the species claimant's side. Such a result would, at a minimum, appear to be unfair.

Comment 175: Six comments urge

Comment 175: Six comments urge that a one-way test is necessary so that a senior party applicant may attack a junior party patentee with a dominating claim.

Answer: The problem the comments identify as appropriate for an interference is instead a case of claim dominance. The remedy consequently is not an interference, but may be a

reexamination or some other patentability or validity contest. The Office has proposed a post-grant review process that would provide an appropriate forum for addressing such concerns. United States Patent and Trademark Office, The 21st Century Strategic Plan at 11 (updated 3 February 2003). The Office remains steadfast in its position that an interference is not a post-grant cancellation proceeding.

Comment 176: One comment notes that foreign priority proofs are treated differently under 35 U.S.C. 102(g)(1) and (g)(2). According to the comment, this difference violates treaty obligations by placing the foreign patentee at a disadvantage under 35 U.S.C. 102(g)(2). The comment urges that the Office has the initial responsibility to provide a remedy by extending the jurisdiction for interferences to cover situations that otherwise only fall within 35 U.S.C. 102(g)(2).

Answer: Even assuming the comment is correct, the problem lies in the legislative decision to treat outcomes based on 35 U.S.C. 102(g)(1) and (g)(2)differently. The effect of following the comment's suggestion would be to eliminate a distinction that the statute was only recently amended to create. The only plausible reading of 35 U.S.C. 102(g) is that Congress intended foreign priority proofs to be treated differently depending on the situation in which the issue arises. Consequently, the comment would be more appropriately directed to Congress.

Comment 177: One comment seeks clarification about whether unpatentable claims, particularly claims that are unpatentable as the result of a threshold motion, would be taken into consideration in determining whether there are interfering claims.

Answer: Ordinarily, claims that are unpatentable would not be placed into an interference. See § 41.102; Brenner v. Manson, 383 U.S. 519, 528 n.12 (1966) (observing that when a claim is unpatentable on its face, a priority contest need not "inexorably take place"). Similarly, if all interfering claims become unpatentable as a result of a threshold motion, judgment in the interference is justified. See Berman v. Housey, 291 F.3d 1345, 1351, 63 USPQ2d 1023, 1027 (Fed. Cir. 2002) (affirming a judgment against a party with claims barred by 35 U.S.C. 135(b)).

Comment 178: One comment suggests that § 41.203(b) be modified to have the notice of declaration set forth the basis for any claim correspondence or accorded benefit.

Answer: A similar effort was made in former § 1.609 (1998) to have the examiner explain the basis for

correspondence. The rule was subsequently withdrawn in the face of public complaints that it was delaying the declaration of interferences without providing much real benefit to the parties. While some explanation is required before a claim can be finally rejected, the declaration simply creates presumptions that are developed through motions. No party is subject to a rejection or cancellation of its claims without having had an opportunity to address the presumptions in the declaration.

Comment 179: Two comments address § 41.203(d) regarding the addition of a patent or application to the interference. One comment questions what happened to substituting applications under § 1.633(d) (2003) and also seeks guidance on when a motion to add a patent or an application would be timely.

Answer: The suggestion to add an application or a patent under § 41.203(d) could be raised any time, but is more likely to be granted if it is raised early in an interference. The intent of the rule is that it work like the decision to declare an interference, hence it only addresses the addition of a patent or application. A substitution of an application could be accomplished by moving to add a second application with an interfering claim and by cancelling the involved claims in the first application contingent on the addition of the second application to the interference.

Comment 180: A second comment notes that § 41.203(d) permits the addition of non-party applications or patents. While the comment approves, it suggests requiring the movant to show that the claims of the added patent or application are patentable.

Answer: The suggestion is not adopted. A proceeding in which the third party is not a participant is not a good place to explore the patentability of the third party's claims.

Comment 181: Five comments address § 41.204(a) regarding priority statements. Four of the comments urge that the rule would require too much information to be provided too early in the proceeding and suggest a return to current practice under §§ 1.621-1.628 (2003). One comment requests clarification about the nature and amount of documentary support required for the priority statement.

Answer: Section 41.204(a) is amended to clarify that any party that will put on a priority case must file a priority statement. It has also been amended to list specific requirements for the priority statement. Section 41.204(a) still requires the party to state the bases on

which it believes that it is entitled to relief. Such bases might include an intent to prove derivation or to move to be accorded benefit of an additional constructive reduction to practice.

Comment 182: One comment expresses concern that senior parties must file a priority statement and suggests that parties be bound by their preliminary statements.

Answer: Parties are bound by their preliminary statements (§ 41.120(b)). Senior parties do not have to file a priority statement if they do not intend

to put on a priority case.

Comment 183: One comment suggests that § 41.204(b) regarding the statement of the basis for relief for substantive motions is redundant with § 41.121(c)(1). It recommends replacing the notice with a list of motions intended to be filed with the basis for each motion as is required under current practice.

Answer: The rule has been restated in terms of a motions list, although the list will require more detail than is often provided on current lists. The list is not a substitute for a motion, but it must provide sufficient detail to place the Board and the opponent on notice of the precise relief sought. The Board needs adequate notice to facilitate scheduling. Moreover, detailed motions lists can lead to other efficiencies, such as stipulations from the opponent.

Comment 184: One comment opposes § 41.207(a)(1) regarding the presumption of the order of invention for priority. According to the comment, if two parties have identical dates for constructive reduction to practice and neither elects to put on a priority case, then the rule suggests that both would lose, while the comment believes that a patent should issue to both.

Answer: The rule codifies case law that establishes that when both parties have the same date of constructive reduction to practice, neither party is entitled to a presumption of priority. Van Otteren v. Hafner, 278 F.2d 738, 740, 126 USPQ 151, 152 (CCPA 1960) (question of joint invention); Lassman v. Brossi, 159 USPQ 182, 184 (Bd. Int. 1967) (in which both parties lost when neither established priority).

Comment 185: One comment opposes the extension under § 41.207(a)(2) of the clear and convincing evidence standard to instances where the junior party applicant first files after the publication of the senior party's application. According to the comment, the use of a higher evidentiary standard is tied to the presumption of patent validity under 35 U.S.C. 282.

Answer: The evidentiary standard for the priority case of an applicant that

cannot add a claim Federal Register/Vol. 69, No. 155/Thursday, August 12, 2004/Rules and Regulations

filed after the opponent's patent issued is the clear and convincing evidence standard. Price v. Symsek, 988 F.2d 1187, 1190-91, 26 USPQ2d 1031, 1033 (Fed. Cir. 1993). In Price, the court rejected the previously applied beyond a reasonable doubt standard as inconsistent with intervening Supreme Court precedent. The court cited the presumption of validity as the reason for using a higher standard. The Price decision did not purport to be instituting the use of a higher standard in such cases; rather, it was following older precedent. 988 F.2d at 1192 n.2. 26 USPQ2d at 1035 n.2. The older precedent provides reason to believe that the presumption of validity is not the only, or even the primary, reason for using a higher evidentiary standard.

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The best reason for believing that the presumption of validity is not the primary basis for the higher evidentiary standard is that not all patents in interferences benefit from the higher standard. Indeed, the higher standard is the exception and not the rule. "It is important to bear in mind that merely because one of the parties has an issued patent does not mean that the other party must prove his case by [a higher evidentiary standard]." C.W. Rivise & A.D. Caesar, 3 Interference Law & Practice at section 467 (1947); accord Bosies v. Benedict, 27 F.3d 539, 541-42, 30 USPQ2d 1862, 1864(Fed. Cir. 1994) (distinguishing Price). Moreover, the higher standard does not apply to questions that do not bear directly on priority. 3 Interference Law & Practice at § 471; see also *In re Etter,* 756 F.2d 856, 857, 225 USPQ 1, 4 (Fed. Cir. 1985) (in banc) (clear and convincing evidence standard does not apply to patent claims under reexamination)

While *Price* rejected the older evidentiary standard, it did not reject the reasons the older precedent gave for using a higher standard. 988 F.2d at 1192 n.2 & text, 26 USPQ2d at 1035 n.2 & text. That precedent recognized various reasons for the higher standard. Walker v. Altorfer, 111 F.2d 164, 167, 45 USPQ 317, 320 (CCPA 1940) (one of the cases Price cites in n.2). Among the reasons discussed were concerns about spurring and the degradation of evidence after a long delay, 111 F.2d at 168, 45 USPQ at 320. Both of these factors apply in the case of published applications as well.

Typically applications are published 18 months after their earliest claimed benefit date, 35 U.S.C. 122(b)(1), so most late filers would have to have delayed at least 18 months. As the Court of Customs and Patent Appeals cautioned in Horwath v. Lee, 564 F.2d 948, 950, 195 USPQ 701, 704 (CCPA 1977) (also

cited in Price at n.2), an inventor should file promptly because a delay in filing raises the risk that intervening actions by another may deprive the inventor of a property right. See also 35 U.S.C. 102(e) (extending the definition of prior art to include published applications) and 35 U.S.C. 135(b) (extending the bar to include published applications).

Section 41.207(a)(2) is consistent with the patent statutes in treating published applications like patents. Unlike the statutes, however, § 41.207(a)(2) does not create a bar to patentability, but simply extends the existing heightened scrutiny for late filers so that it is triggered by publication of an application as well as issuance of a patent. Use of the clear and convincing evidence standard also furthers the important policy goal of encouraging

prompt filing.

Comment 186: One comment opposes § 41.207(b) with regard to claim correspondence. The comment gives the example of a generic claim that corresponds to both a generic count and a specific count in which there is a split award. In such a case, the generic claim would be unpatentable based on its correspondence to the species count, even though the party "won" the generic count. The comment distinguishes In re Saunders, 219 F.2d 455, 104 USPQ 394 (CCPA 1955), which was discussed in the notice of proposed rule making, because it was an ex parte appeal. The comment also points to Ex parte Hardman, 142 USPQ 329 (BPAI 1964) for the proposition that Saunders does not create a per se rule of unpatentability for generic claims in such cases.

Answer: Although the comment urges that the rule represents a change from current practice, the rule simply formalizes the effect of the estoppel arising out of cases like In re Deckler, 977 F.2d 1449, 1452, 24 USPQ2d 1448, 1449 (Fed. Cir. 1992), in which a party could not subsequently seek claims that were patentably indistinct from the subject matter of the count lost in the interference. As earlier discussed, no one "wins" a count because surviving a priority contest for one count does not mean that one is thereby entitled to a claim. *Kyrides*, 159 F.2d at 1022, 73 USPQ at 63.

In-Saunders, a junior party could not claim a generic invention after losing a species count. Although the case was an ex parte appeal, it arose because Saunders was a junior party who had lost a species count, but not the generic count, making the Saunders case directly relevant. The case law has many examples of parties who having lost interferences try, with varying

degrees of success to either claim around (e.g., In re Johnson, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977)) or to antedate (e.g., In re Zletz, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989)) the subject matter of the lost count. Hardman was correct that Saunders did not create a per se rule of unpatentability for generic claims, but neither does § 41.207(b). It simply creates a presumption that must be addressed.

If a party with a generic claim that corresponds to a species count is concerned about the designation, its remedy is to move to have the generic claim designated as not corresponding to the species count. Often, the motion would be deferred until the priority phase and dismissed unless there were a split award on priority, in which case proof that the generic invention antedates the priority proofs for the lost species count would likely justify relief

Comment 187: Nine comments oppose at least some aspect of the proposed presumption under § 41.207(d) of abandonment, suppression, or concealment when the party's effective filing date is more than one year after the party's actual

reduction to practice.

Answer: The presumption has been deleted as unnecessary. Delays longer than 18 months will often result in a bar to patentability or heightened scrutiny (§ 41.207(a)(2)) anyway so the proposed rule would not have been likely to change the outcome in many interferences.

Under a priority motions practice, abandonment, suppression, or concealment can be raised in the opposition to a priority motion. Any request for additional discovery (§ 41.150(c)) or motion for compelled testimony or production (§ 41.156(a)) should be filed promptly to ensure that is reflected in the opposition.

Comment 188: One comment suggests adding a provision to § 41.208(a)(2) to

address adding counts.

Answer: Section 41.208(a)(2) has been reworded to substitute "definition of the interfering subject matter" for the first occurrence of "count". The point of the rule is to focus parties on using substantive motions to define the range of admissible proofs for priority before the priority phase begins.

Comment 189: Three comments express alarm that priority is addressed as a motion under § 41.208(a)(4). The principal concern appears to be that priority will routinely be decided at the same time as the preliminary motions.

Answer: The rules do not require priority to be decided simultaneously with the preliminary motions. Indeed, FULL TEXT OF CASES (USPQ2D)
All Other Cases

## L'Esperance v. Nishimoto (BdPatApp&Int) 18 USPQ2d 1534 L'Esperance v. Nishimoto

## U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences 18 USPQ2d 1534

Decided May 22, 1989 and February 26, 1991 Interference No. 101,882

#### Headnotes

#### **PATENTS**

1. Practice and procedure in Patent and Trademark Office - Interference - Counts (§ 110.1703)

Practice and procedure in Patent and Trademark Office - Interference - Motions (§ 110.1717)

Motion in which party in interference sought to amend its claims in attempt to distinguish prior art reference and to have amended claims designated as not corresponding to count should have been dismissed, since rules do not provide for amending or adding claims for purpose of having them designated as not corresponding to count, but provide for amending or adding application claim only if proposed claim corresponds to count.

# 2. Patentability/Validity - Obviousness - Relevant prior art - In general (§ 115.0903.01)

Mere reference to claimed feature which is not disclosed by prior art reference and which is not included in count does not per se establish separate patentability within meaning of 37 CFR 1.601(n); rather, question is whether that feature would have been obvious to person of ordinary skill in subject art.

## Case History and Disposition:

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Patent interference no. 101,882, between Chantal L'Esperance and Germain Belanger, patent granted Nov. 4, 1986, no. 4,620,401 (serial no. 06/730,205, filed May 3, 1985), and application of Takashi Nishimoto and Toshihisa Miyata, filed April 9, 1986, serial no. 06/849,856, accorded benefit of Japanese serial no. 76699/1985, filed April 12, 1985. Judgment as to subject matter of count entered against both parties by board, following decision on motions by examiner-in-chief.

## **Attorneys:**

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Charles L. Gholz, Oblon, Fisher, Spivak, McClelland, Maier and Neustadt, Norman F. Oblon, Stanley P. Fisher, Marvin J. Spivak, C. Irvin McClelland, Gregory J. Maier, Arthur I. Neustadt, Robert C. Miller, Richard D. Kelly, James D. Hamilton, Eckhard H. Kuesters, and Robert T. Pous, Arlington, Va., for Nishimoto et al.

**Opinion By:** 

Caroff, examiner-in-chief.

**Text** 

### **Decision on Motions**

## May 22, 1989

The following preliminary motions under 37 CFR 1.633 have been filed:

- (1) Nishimoto et al (N) motion to designate its claims 3, 5-8, 21-22, 24, 33-35, 39-40, 47 and 49-51 as not corresponding to the count (Paper No. 9). Unopposed.
- (2) N motion for judgment (Paper No. 10) of unpatentability to L'Esperance et al (L) of claims 1-10 under 35 USC 112, second paragraph. Opposition by L (Paper No. 14); Reply by N (Paper No. 15).
- (3) L motion for judgment (Paper No. 13):

A. of unpatentability to N of claims 3 and 5-59 under 35 USC 112, first paragraph. Opposition by N (Paper No. 17); Reply by L (Paper No. 22);

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- B. of unpatentability to N of claims 3 and 5-59 under 35 USC 102(b) and/or 35 USC 103 in view of Offenlegungsschrift 1936078 (Karner). Opposition by N (Paper No. 16); Reply by L (Paper No. 21).
- (4) N motion under §1.633(i) to amend its claims 20, 36 and 52-59 (Paper No. 18). Unopposed.
- (5) N motion to be accorded benefit of the filing date of Japanese application 76699/1985 as to its proposed amended claims (Paper No. 20). Opposition by L (Paper No. 24).
- (6) L motion to designate its claims 2-4, 6 and 11 as not corresponding to the count (Paper No. 13½). Opposition by N (Paper No. 19); Reply by L (Paper No. 23).

## Motion (3)B

The motion is granted. N concedes that its claims 9-18, 23-25, 29, 32, 37-39, 41-43 and 48 are unpatentable over Karner. See Paper No. 16. By conceding that claim 9 is unpatentable, N in effect concedes that the invention defined by the count is also unpatentable since claim 9 is identical to the count. In view of the concession of unpatentability by N as to its generic claims and the count, the remaining claims of N, i.e., claims 3, 5-8, 19-22, 26-28, 30-31, 33-36, 40, 44-47 and 49-59, are considered to be unpatentable over the prior art as well. In this regard, it is noted that the Commissioner through his delegate, the Primary Examiner, determined at the outset of the interference that all of the pending claims of N correspond to the count or, in other words, define the "same patentable invention" as the count. See §1.601(f) and (n). Therefore, it is presumed that none of the claims of N define a separate patentable invention with respect to the count, and the burden of persuasion rests upon the party, here N, urging the contrary. Cf. Case v. CPC International, Inc., 730 F.2d 745, 221 USPQ 196 (Fed. Cir. 1984), cert. denied, — U.S. —, 224 USPO 736 (1984). Mere reference by N to claimed

features and alleged advantages which are not disclosed by Karner and not included in the count does not per se establish "separate patentability" within the meaning of §1.601(n). Rather, the question is whether those features and advantages would have been obvious to a person of ordinary skill in the art. This question has not been adequately addressed by N. N has failed to present a thorough analysis of Karner in light of other prior art references of record, including prior art cited during ex parte prosecution of the parties' involved applications, in accordance with the guidelines set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). For example, with respect to claims 3 and 5-8, it appears that the Schmit reference was relied upon during ex parte prosecution to establish the obviousness of wrapping a twisted cord around a core element. With respect to claims 33, 46-47 and 51-59, it appears that Riley was relied upon to show alternative materials which are used in producing reinforcing fibers. With respect to claims 19-22, 26-28, 30-31, 34-36, 40, 44-45 and 49-50, N has failed to present any evidence to establish that the selection of specific system parameters and materials would be anything other than an obvious matter of routine design choice. Mere argument by an attorney is of no probative value. Meitzner v. Mindick, 549 F.2d 775, 193 USPQ 17 (CCPA 1977), cert. den., 434 U.S. 854, 195 USPQ 465 (1977). The undersigned Examiner-in-Chief hereby moves sua sponte under 37 CFR 1.610(e), 1.633(a) and 1.641 for judgment on the ground that all the claims of L corresponding to the count are unpatentable under 35 USC 102(b) and/or 35 USC 103 over the prior art, particularly Karner. As pointed out by N in its opposition, L claims 1, 5, 7-10 and 12 are identical to N claims 9 and 11-16, which claims are argued by L in its motion to be unpatentable over Karner. Therefore, it appears that L at least tacitly concedes that its identical claims 1, 5, 7-10 and 12 are also unpatentable over Karner. Since L claim 1 is identical to the count, it is presumed that all of the claims of L which were designated by the Primary Examiner as corresponding to the count, including claims 2-4, 6 and 11, are unpatentable over the prior art as well absent evidence of separate patentability essentially for the reasons discussed above relative to N claims 3, 5-8, 19-22, 26-28, 30-31, 33-36, 40, 44-47 and 49-59. In this regard, it is noted that L, like N, has failed to analyze its claims in the light of known prior art in addition to the Karner reference, and has failed to present any credible evidence to establish that any differences between the prior art and the claims in issue would not have been within the expected skill of a person versed in the subject art. Graham v. John Deere Co., supra.

## Motions (1) and (6)

These motions are *denied* essentially for the reasons set forth above with respect to motion 3(B). A movant seeking to have claims designated as not corresponding to a count has the burden of making a case for separate patentability. 37 CFR 1.637 (c)(4)(ii). As noted above, merely pointing

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out differences between each of the claims in issue and the count does not *per se* establish separate patentability or, in other words, establish that the asserted differences represent subject matter which would not have been obvious to a person of ordinary skill in the art.

## Motions (2) and (3)A

These motions are dismissed as moot in view of the finding, supra, that all of the claims of each party which correspond to the count are unpatentable over the prior art.

## Motion (4)

The motion to amend claims is *denied* since the involved claims, even if amended as proposed, are considered to be unpatentable for the reasons set forth above with respect to motion (3)B.

## Motion (5)

The motion is *dismissed* as most in view of the denial of motion (4).

#### Order to Show Cause

In view of the finding, supra, that all of the claims of each party which correspond to the count are unpatentable over the prior art, notice is hereby given pursuant to the provisions of 37 CFR 1.640(d) that judgment on the record as to those claims will be entered against both the junior party and the senior party unless they shall within *twenty (20) days* from the date of this decision, show cause why such action should not be taken. Should either party elect to show cause why judgment should not be rendered, attention is directed to 37 CFR 1.640(e) and the guidance provided in the Commissioner's Notice of January 6, 1987, "Interference Practice: Response to Order to Show Cause under 37 CFR 1.640", 1074 O.G. 4.

Should either party wish to present its views under 37 CFR 1.641 regarding the finding of unpatentability, it may do so as part of its response to the show cause order, or, instead, merely file a request that final hearing be set to review the finding accompanied by a motion requesting a testimony period, if the party desires to take testimony. The preliminary statements filed by each party remain sealed on the record.

#### Decision

## February 26, 1991

## Judge:

Before Boler, Parson, and Caroff, examiners-in-chief.

## **Opinion By:**

Caroff, examiner-in-chief.

#### Text

This interference involves a patent of the junior party, L'Esperance et al (L'Esperance), and an application of the senior party Nishimoto et al (Nishimoto). The L'Esperance patent is assigned to Societe Nationale De L'Amiante of Canada, and the Nishimoto application is assigned to Dainihon Glass Industry Co. Ltd., Shimizu Construction Company Ltd. and Kyozin Rope Manufacturing Company Ltd., all of Japan. The subject matter involved in this interference relates to a structural rod which may be

used for reinforcing a mass of concrete. The following count, the only count involved in this interference, is reproduced here as illustrative of the subject matter in issue:

#### Count I

A structural rod for reinforcing a mass of concrete material comprising:

- (a) a non-metallic non-electrically conductive cylindrical core composed of a plurality of continuous fibers oriented substantially in the longitudinal axis and bound to one another by a thermosetting resin; and
- (b) embossment means on said core, being formed of a plurality of continuous fibers helically wound around said core and impregnated with a thermosetting resin; said thermosetting resin achieving a strong bond between the core and the fibers helically wound thereabout so as to prevent relative movement between said core and said embossment means;

said embossment means defining a mechanical anchorage bond with concrete material when said rod is embedded in said mass of concrete material.

The claims of the parties which have been designated as corresponding to this count are:

L'Esperance: Claims 1-12

Nishimoto: Claims 3, 5-59

L'Esperance claim 1 and Nishimoto claim 9 correspond exactly to the count. The issues before us concern the propriety of the findings in the Decision on Motions of May 22, 1989 (Paper No. 34) as to the motions which were designated therein as 1, 2, 3A, 3B, 4 and 6. 1 Also, we shall consider the motion to strike certain portions of the reply brief (Paper No. 45) brought by Nishi

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moto on November 9, 1989 as well as the corresponding opposition (Paper No. 47) and reply (Paper No. 46).

Neither party requested a testimony period (see Paper No. 38), but both did file briefs and appeared, through counsel, at final hearing.

After a thorough review of the aforementioned Decision on Motions in light of the arguments presented by opposing counsel in the briefs and at final hearing, we find ourselves in substantial agreement with the Examiner-in-Chief on all particulars except for the disposition of L'Esperance claim 11. Accordingly, with but one exception, we adopt the position taken by the Examiner-in-Chief as our own with respect to each of the preliminary motions at issue.

The following discussion of individual motions is presented to highlight the reasoning upon which our conclusions are based.

## Nishimoto's Motion to Strike

The subject motion seeks an order striking footnote 1; page 12, line 13-page 17, line 25; page 23, line 4-page 26, line 8; Appendix B; and Appendix C in the reply brief. We shall grant the motion in question essentially for the reasons presented by Nishimoto in support thereof. Accordingly, none of the aforementioned parts of the reply brief have been considered by us in our review of the Examiner-in-Chief's Decision on Motions. For emphasis, we note that the parts of the reply brief in question relate to either

preliminary motion 1 or preliminary motion 3A. Motion 1 was not opposed by L'Esperance and motion 3A was dismissed by the Examiner-in-Chief. The Examiner-in-Chief gave due notice (Paper No. 38) that L'Esperance would not be entitled to argue such motions on the merits at final hearing. Moreover, a reply brief is an inappropriate vehicle for introducing evidence, i.e., a new reference (L'Esperance reply brief - Appendix B) or declaration (L'Esperance reply brief - Appendix C), for the first time. In this regard, note that 37 CFR 1.671(e) and 1.682 require that such evidence must be introduced during the party's relevant testimony period and L'Esperance did not request a testimony period (see Paper No. 38).

#### **Motion 4**

[1] In the subject motion, Nishimoto apparently sought to amend its claims 20, 36, and 52-59 in an attempt to distinguish over the prior art Karner reference and to have the amended claims designated as not corresponding to the count or, as phrased in the Nishimoto brief (page 19), to "degroup" those claims from the count. Although the motion was denied, it is our view that the motion should have been dismissed since the rules do not provide for amending or adding claims for the purpose of having them designated as not corresponding to the count. Specifically, the rules provide for amending or adding an application claim only in the situation where the proposed claim corresponds to the count. Note, for example, that §1.633(c)(2) provides for amending or adding claims to be designated as corresponding to the count; whereas §1.633(c)(4), the section providing for designation of claims as not corresponding to a count, makes no reference to amending or adding claims. Moreover, §1.637(c)(2)(ii), which relates to §1.633(c)(2), requires that the proposed claim must define the same patentable invention as the count, i.e., must correspond to the count (§1.601(f)). Thus, it should be apparent that an involved application claim can be amended during an interference proceeding only if the resulting claim corresponds to the count and, conversely, a motion under §1.633(c)(4) can only be brought with respect to an already existing claim which was originally designated as corresponding to a count.

Accordingly, we shall not consider the amended versions of claims 20, 36 and 52-59 which were proposed by Nishimoto. When *ex parte* prosecution resumes after termination of the interference, Nishimoto may request that the primary examiner consider the amended claims consistent with our opinion.

## Motions 1, 3B and 6

The question of the separate patentability of claims with respect to the count (motions 1 and 6) and the question of patentability of claims over the Karner reference (motion 3B) are closely related inasmuch as both parties apparently concede that the invention defined by the count is unpatentable over Karner. Accordingly, we choose to address the issues raised in motions 1, 3B and 6 together under one heading.

Initially, we note that L'Esperance does not dispute that its claims 1-3, 5-10 and 12 correspond to the count and are unpatentable. Similarly, Nishimoto does not dispute that its claims 9-18, 23-25, 29, 32, 37-39, 41-43 and 48 correspond to the count and are unpatentable. Additionally, from the standpoint of patentability, Nishimoto claims 19-20, 26-28, 30-31, 36, 44-46 and 52-59 2

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stand or fall with the count since they have not been separately argued and Nishimoto did not move to "degroup" these claims. At any rate, failure to so move would preclude any argument at final hearing that there is a patentable distinction between claims and the count. Cf. Kwon v. Perkins, 6 USPQ2d 1747, 1751 (BPAI 1988).

[2] Our conclusions regarding the patentability of the remaining claims in issue 3 are discussed below. With the invention defined by the count being unpatentable over Karner, any particular claim corresponding to the count is presumed to embrace subject matter which does not constitute a separate patentable invention absent a convincing showing to the contrary. In other words, a party has the burden of establishing by a preponderance of evidence that any argued claim is separately patentable or patentably distinct with respect to the prior art in accordance with the guidelines set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). See §1.637(c)(4)(ii) and §1.601(n). 4 Mere reference to a claimed feature which is not disclosed by Karner and not included in the count does not *per se* establish "separate patentability" within the meaning of §1.601(n). Rather, the question is whether that feature would have been obvious to a person of ordinary skill in the subject art. Our discussion of the remaining claims in issue now follows:

## (a) L'Esperance claim 4

L'Esperance argues that the feature embodied in claim 4 of "enveloping" a core and embossment means with a layer of thermosetting resin is advantageous or desirable. To wit, L'Esperance asserts that concrete is highly corrosive to glass material, and that an enveloping resin layer will prevent such corrosion. This argument is entirely unpersuasive since it is not commensurate with the scope of claim 4. In this regard, we note that the claim is not limited to the use of a core or embossment means which is composed of a glass material. Moreover, we find nothing in the record which supports the assertion that concrete corrodes glass or that an enveloping resin layer will prevent such corrosion. Even if claim 4 were limited to use of glass material, we note that the Karner disclosure (translation page C-5, lines 8-12) indicates that the resin "completely fills out the sheath" which at least suggests the "enveloping" feature of claim 4.

## (b) L'Esperance claim 11

We agree with L'Esperance that claim 11, by requiring the inclusion of "aggregates randomly set in" an enveloping resin layer, defines an invention which is patentably distinct from the prior art. Certainly, the prior art does not teach or suggest the inclusion of aggregates as part of a structural reinforcing rod. Nishimoto's allegation of inherency to the contrary notwithstanding, we find no evidence that any outer layer of resin on a prior art reinforcing rod would be in a tacky condition when the rod is embedded in a mass of concrete. Thus, we cannot agree with Nishimoto that aggregate in surrounding concrete would inherently get mixed into any outer layer of resin on a reinforcing rod. In view of the foregoing determination that claim 11 represents a patentably distinct or separate patentable invention, this interference is being *redeclared* in a concurrent paper to indicate that claim 11 does not correspond to the count.

## (c) Nishimoto claims 3 and 5-8

The subject claims have not been argued separately by Nishimoto and, therefore, are considered to stand or fall together with basic claim 5. *In re Nielson*, 816 F.2d 1567, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

At the outset, we note that the Examiner-in-Chief apparently relied on Schmit as a secondary reference. However, with respect to claim 5, we find that a *prima facie* case of obviousness under 35 USC 103 is established by reference to Schmit alone. To support a finding of patentability, Nishimoto argues that: (1) Karner does not teach or suggest that the glass fibers or glass yarn strands which are wrapped around a reinforced core can be twisted together and (2) while it may have been within the skill of an ordinary artisan to determine the pitch of twisted material necessary to optimize desired properties with regard to the subject matter of

#### Page 1539

Schmit (i.e., a reinforced vulcanized tire), there is no evidence of record that one of ordinary skill in the art to which the subject claims pertain (i.e., reinforcement of materials such as concrete and rock) would have arrived at a pitch within the specific numerical range set forth in claim 5 from a perusal of Schmit. Each of these arguments is not convincing. With respect to the first argument, it is Schmit not Karner which essentially discloses the basic structure described in claim 5. In this regard, attention is directed to Schmit at col.2, 1. 53-col. 3, 1. 2. In particular, Schmit teaches that yarn filaments which are wrapped around a reinforced core can be twisted together. With respect to the second argument, it is noted that claim 5 is not limited to any particular structural environment. In other words, there is nothing in claim 5 which limits the described reinforcing member to a concrete or rock environment. In this respect, claim 5 appears to read on a reinforcing member which is capable of being used to reinforce a tire as in Schmit. Nishimoto has not shown that the pitch range recited in claim 5 yields unexpected results or is useful only in one particular environment. For the foregoing reasons, claims 3 and 5-8 are viewed together as being unpatentable over Schmit.

## (d) Nishimoto claims 21 and 22

Although argued separately, these claims are treated together since the determination of their status involves the same basic considerations. Nishimoto argues that the prior art does not teach or suggest the structure recited in claim 21 ("embossment means comprises a plurality of separate, spaced turns") or claim 22 ("embossment means comprises a plurality of spaced turns ... connected to one another in the longitudinal direction of said core"). We agree with L'Esperance, however, that the particular configuration recited in each of these claims appears to be of no patentable significance. Nishimoto has failed to present any evidence that the claimed configurations are something more than mere design variations well within the ordinary skill of those versed in the art. Nor has Nishimoto established or even argued that use of the claimed configurations in lieu of that disclosed in the prior art solves a particular problem or otherwise provides a particular benefit. Cf. *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

## (e) Nishimoto claims 33 and 47

As above, claims 33 and 47, although separately argued, are treated together here since they relate to similar subject matter, namely the use of carbon fibers or filaments to form components of a reinforcing member. As indicated by the Examiner-in-Chief on page 3 of his Decision on Motions, the Riley reference suggests that carbon fibers may be used as an alternative reinforcing material in lieu of glass fibers. Thus, we have no doubt that a person of ordinary skill in the art would have found it prima facie obvious to construct a prior art reinforcing member from components composed of carbon filaments. Nishimoto has not shown otherwise. We see little merit in the argument that the reinforcing fibers in Riley are distributed generally homogeneously throughout a cementitious mass. Clearly, Riley is not relied on to show the particular structure claimed by Nishimoto. It is Karner and the count which describe a reinforcing member including an embossment means wound around and bound to a core. When resolving questions of obviousness arising under 35 USC 103, it is appropriate to consider what the prior art references, taken collectively, would have suggested to a person of ordinary skill in that art. Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 226 USPQ 881, 886-87 (Fed. Cir. 1985); In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

## (f) Nishimoto claims 34 and 35

With respect to these claims, Nishimoto argues that the prior art does not teach any particular core fiber distribution. This argument fails not only because a particular fiber distribution would be, *prima facie*, an obvious matter of design choice, but also because the argument is not commensurate with the scope of the claims. In this regard, note that claim 29 requires only that "at least some" of the core fibers are reinforcing fibers. This does not exclude the possibility that all the core fibers are reinforcing fibers. Therefore, claims 34 and 35, which depend from claim 29, are not limited to a particular distribution where reinforcing fibers are present only in one part of the core.

## (g) Nishimoto claim 40

With respect to claim 40, Nishimoto argues that the prior art does not teach any particular concentration of resin impregnated in an embossment means projecting from a reinforcing member. This argument is not sufficient to overcome the *prima facie* case of obviousness since the selection of an opti

#### Page 1540

mum range of values for a particular system parameter is generally considered to be within the realm of ordinary skill. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980); *In re Reni*, 419 F.2d 922, 164 USPQ 245 (CCPA 1970); *In re Mostovych*, 339 F.2d 455, 144 USPQ 38 (CCPA 1964).

## (h) Nishimoto claims 49 and 50

With respect to these claims, Nishimoto argues that the prior art does not teach or suggest the particular core configurations described in the subject claims. This argument is unpersuasive essentially for the same reasons presented above with respect to claims 21 and 22. Moreover, we note that claim 1 of Karner suggests that a reinforcing rod may

have "varied cross section shapes".

## (i) Nishimoto claim 51

As with claims 33 and 47 (see the previous discussion of these claims), we agree with the Examiner-in-Chief that a person of ordinary skill in the art would have found the subject matter of claim 51 prima facie obvious from Karner or the count, with each taken in view of Riley. In this regard, it is noted that Riley (col. 2, 1. 23-34) discloses a number of alternative materials, including steel, which may be used for producing reinforcing fibers. Thus, it would have been obvious to construct a prior art reinforcing member from a core component composed at least in part of steel fibers.

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We note that claim 51 does not characterize the recited "steel reinforcing member" in structural terms. Accordingly, claim 51 reads on a reinforcing rod having a core composed entirely of steel fibers wherein the exterior fibers could be said to be arranged around a "steel reinforcing member" (i.e., the interior fibers). In any event, our conclusion would not change even if claim 51 were further limited to specifically require that the core be composed of different materials, namely a "steel reinforcing member" surrounded by fibers other than steel fibers. In such an eventuality, the *prima facie* obviousness of the combination would flow from the expectation of obtaining additive results. Cf. *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980).

#### Motions 2 and 3A

These motions were dismissed as moot by the Examiner-in-Chief in his Decision on Motions. As pointed out in Paper No. 38, issues raised in dismissed motions are ordinarily not entitled to be raised at final hearing. Cf. Land v. Dreyer, 155 F.2d 383, 69 USPQ 602 (CCPA 1946). We find no compelling reason, and neither party has provided any, why motions 2 and 3A should be considered on the merits in view of the fact that all the claims to which the motions relate have been found unpatentable over the prior art. Accordingly, we find that the motions in question were properly dismissed and will not be further considered here.

## Judgment

For the foregoing reasons, judgment as to the subject matter of the count is hereby entered against both parties.

Accordingly, Chantal L'Esperance and Germain Belanger are not entitled to their claims 1-10 and 12 corresponding to the count, and Takashi Nishimoto and Toshihisa Miyata are not entitled to their claims 3 and 5-59 corresponding to the count.

Footnote 1. We note that motions 1 and 4 were not opposed by L'Esperance and, accordingly, we have not considered any arguments presented by L'Esperance in his brief or reply brief which pertain to those motions. §1.655(b).

Footnote 2. Note that this group of claims includes unamended claims 20, 36 and 52-59. With reference to the proposed amendment of these claims, see the discussion with respect to motion 4, supra.

Footnote 3. The remaining claims in issue are L'Esperance claims 4 and 11 and Nishimoto claims 3, 5-8, 21-22, 33-35, 40, 47, 49-51.

Footnote 4. The "prior art" relied upon by the Examiner-in-Chief in his Decision on Motions evidently consists of the count under §1.601(n) or, alternatively, Karner (Offenlegungsschrift 1936078) with each taken either with or without Schmit (U.S. Patent No. 4,458,475) or Riley (U.S. Patent No. 4,133,928).

Copies of all the prior art references and the argued claims as well as a translation of the Karner reference appear as appendices attached to the L'Esperance and Nishimoto briefs.

- End of Case -

#### FULL TEXT OF CASES (USPQ FIRST SERIES)

# Ex parte HARDMAN, 142 USPQ 329 (BdPatApp&Int 1964)

## Ex parte HARDMAN

## (BdPatApp&Int) 142 USPQ 329

Patent issued July 28, 1964
Opinion dated Sept. 23, 1963
U.S. Patent and Trademark Office, Board of Patent Appeals and
Interferences

#### Headnotes

#### **PATENTS**

1. Disclaimer--In general (§ 32.1)

Patentability -- Anticipation -- Involving interference (§ 51.213)

Species are in prior art by virtue of applicant having disclaimed or abandoned interference contest as to them.

## 2. Board of Appeals -- Procedure and practice (§ 19.45)

On appeal from rejection of claims, Board may consider stipulation of testimony present in interference in which application had been involved.

## 3. Interference--Priority (§ 41.70)

Particularly where interference is with a patent, with applicant copying all claims from patent which he can make, and involving both generic and species claims, priority as to generic invention by applicant is not necessarily disproved by his not being first inventor of species claimed by patentee, since applicant was first to possess generic aspects of invention by conception and reduction to practice of other species falling under claimed genus.

#### Particular patents -- Chemical Compounds

3,142,684, Hardman, N-(Beta-Cyanoethylalkyl)-2-Arylene-Thiazole Sulfenamide, claims 2 and 3 of application allowed.

## Case History and Disposition:

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Appeal from Group 120.

Application for patent of Albert F. Hardman, Serial No. 753,628, filed Aug. 7, 1958. From decision rejecting claims 2 and 3, applicant appeals (Appeal No. 122-20). Reversed. Attorneys:

R. L. MILLER, JAMES B. HOLDEN, JAMES M. WALLACE, JR., and V. G. PARKER, all of Akron, Ohio, for applicant.

### Judge:

Before FEDERICO and ROSA, Examiners in Chief, and STONE, Acting Examiner in Chief.

## **Opinion Text**

## **Opinion By:**

ROSA, Examiner in Chief.

This is an appeal from the action of the examiner finally rejecting claims 2 and 3. Claim 5, the only other claim in the case, stands allowed.

The appealed claims are reproduced below:

noethyl - 3alkyl - 2 - arylenethiazolesul-

- 2. As a new composition beta-cyafenamide in which the alkyl group contains from 1 to 5 carbon atoms.
- 3. As a new composition beta-cyanoethyl alkyl 2 benzothiazolesulfenamide in which the alkyl group contains from 1 to 5 carbon atoms.

The references relied upon are:

Smith, 2,367,827, Jan. 23, 1945. Moore et al., 2,417,989, Mar. 25, 1947. Carr et al., 2,476,818, July 19, 1949. Smith, 2,514,208, July 4, 1950. Lunt, 2,762,814, Sept. 11, 1956 (filed Nov. 26, 1954). Cherlow, 2,863,867, Dec. 9, 1958.

The subject matter at issue relates to compounds of the formula Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

wherein R 1 is a 2-arylene group and R is an alkyl radical containing from 1 to 5 carbon atoms.

Appellant copied claims 2, 3 and 5 from the Schoene et al. patent and two interferences were declared as a result thereof. Claim 2 of the patent, that is the compound "N-isopropyl-N-beta-cyanoethyl - 2 - benzothiazolesulfenamide," constituted the count in Interference No. 91,019 and appellant filed an abandonment of contest in said interference resulting in its dissolution. Claim 3 and a modified from of claim 5 of the patent formed the counts in Interference No. 89,955, which Interference also involved a third party, in which the counts were:

Count 1: N-cyclohexyl-N-beta-cyanoethyl - 2 - benzothiazolesulfenamide. Count 2: Compounds represented by the formula

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

where R represents an alkyl hydrocarbon radical.

Appellant disclaimed the subject matter defined by Count 1 in this interference. Priority of the invention of the subject matter as defined in Count 2 was awarded to appellant as the patentees Schoene et al. filed an abandonment of the invention with respect to this count.

We have thus the unusual situation where it has been determined that ap

#### Page 330

pellant is not the first inventor of one species falling under the genus defined by the appealed claims, that is N-isopropyl - N - beta - cyanoethyl - 2 - benzothiazolesulfenamide, as well as that he is not the first inventor of the analogous species N-cyclohexyl - N - beta-cyanoethyl - 2 - benzothiazolesulfenamide, and yet appellant urges that he is entitled to the broad generic claims now on appeal.

- [1] The examiner has rejected the appealed claims as unpatentable over the issue of Interference No. 91,019, and over Count 1 of Interference No. 89,955. Smith, Moore et al., Carr et al., Lunt and Cherlow are further relied upon to show the art-recognized general equivalency of N-alkyl and N-cycloalkyl benzothiazole sulfenamides. Since the cycloalkyl and isopropyl species are in the prior art by virtue of appellant having disclaimed or abandoned contest as to these species, it is urged by the examiner that the alkyl species as defined in the appealed claims would thus be obvious.
- [2] Under the factual situation present in this case we cannot sustain the indicated rejection. In the affidavit under Rule 204, in the nature of an affidavit under Rule 131, submitted in this case, as well as in the stipulation of testimony present in Interference No. 89,955, and which stipulation we may consider, Ex parte Bowyer, 1939 C.D. 5, 505 O.G. 759, 42 USPQ 526, appellant has shown that he conceived and reduced to practice

the generic invention defined by the appealed claims prior to July 27, 1954, the effective date of the Schoene et al. patent, by virtue of having made prior to said date various species falling under the claimed genus, i.e., N-alkyl-N-beta-cyanoethyl-2-benzothiazolesulfenamides wherein alkyl is ethyl, as claimed in allowed claim 5, methyl n-propyl and t-butyl, as well as cyclohexyl and isopropyl. The stipulation further attests to the fact that appellant was in possession of the generic concept of the invention prior to July 27, 1954, by having conceived of sulfenamides of the claimed configuration substituted with branched chain radicals, such as isopropyl, isobutyl, secondary butyl, tertiary butyl, secondary amyl, etc., followed by a reduction to practice of the isopropyl species. The examiner does not question the adequacy of the affidavit and stipulation to establish priority of the generic invention, and in fact concedes as much, but nevertheless argues that since appellant is not the first inventor of at least one species falling within the scope of the claimed genus, appellant is not entitled to obtain a generic claim.

[3] We do not consider this to be a just and equitable conclusion. Particularly in a situation where the interference is with a patent, an applicant copying all the claims from the patent which he can make, and as he must (Rule 205(a)), and involving both generic and species claims, priority as to the generic invention by applicant is not necessarily disproved by his not being the first inventor of one species, which species is specifically claimed by the patentee, when it has been fully established that applicant in fact was the first to possess the generic aspects of the invention. In re Saunders, 1955, 104 USPQ 394. There is no indication of record that either of the two species was invented by the other party prior to the time that appellant made any one of the other species, or prior to the time that it may be considered appellant made the generic invention.

We note an article by Maurice W. Levy, entitled "Ex parte Proof of Priority of the Chemical Genus" appearing in the Journal of the Patent Office Society, Volume 26, 1944, pages 576 to 592, discussing similar situations to the one we are now confronted with. Although none of the cases discussed by the author have the same facts as present herein, we are nevertheless of the view that the rationale in Ex parte Prutton, Patent file No. 2,223,127, 47 USPQ 397, and Ex parte Hjerpe et al., 48 USPQ 148, should be followed here. We consequently reverse the decision of the examiner.

- End of Case -

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## 2138.01 Interference Practice [R-3] - 2100 Patentability

2138.01 Interference Practice [R-3]

## I. < 35 U.S.C. 102(g) IS THE BASIS OF INTERFERENCE PRACTICE

Subsection (g) of 35 U.S.C. 102 is the basis of interference practice for determining priority of invention between two parties. See Bigham v. Godtfredsen, 857 F.2d 1415, 1416, 8 USPQ2d 1266, 1267 (Fed. Cir. 1988), 35 U.S.C. 135, 37 CFR \*>Part 41, Subparts D and E< and MPEP Chapter 2300. An interference is an inter partes proceeding directed at determining the first to invent as among the parties to the proceeding, involving two or more pending applications naming different inventors or one or more pending applications and one or more unexpired patents naming different inventors\*\*. The United States is unusual in having a first to invent rather than a first to file system. Paulik v. Rizkalla, 760 F.2d 1270, 1272, 226 USPQ 224, 225 (Fed. Cir. 1985) (reviews the legislative history of the subsection in a concurring opinion by Judge Rich). The first of many to reduce an invention to practice around the same time will be the sole party to obtain a patent, Radio Corp. of America v. Radio Eng'g Labs., Inc., 293 U.S. 1, 2, 21 USPQ 353, 353-4 (1934), unless another was the first to conceive and couple a later-in-time reduction to practice with diligence from a time just prior to when the second conceiver entered the field to the first conceiver's reduction to practice. Hull v. Davenport, 90 F.2d 103, 105, 33 USPQ 506, 508 (CCPA 1937). See the priority time charts below illustrating this point. Upon conclusion of an interference, subject matter claimed by the losing party that was the basis of the interference is rejected under 35 U.S.C. 102(g), unless the acts showing prior invention were not in this country.

It is noted that **35 U.S.C. 101** requires that whoever invents or discovers is the party who may obtain a patent for the particular invention or discovery. **35 U.S.C. 111** (applicant) or **35 U.S.C. 116** (applicants) set forth the requirement that the actual inventor(s) be the party who applies for a patent or that a patent be applied for on behalf of the inventor. Where it can be shown that an applicant has "derived" an invention from another, a rejection under **35 U.S.C. 102(f)** is proper. *Ex parte Kusko*, 215 USPQ 972, 974 (Bd. App. 1981) ("most, if not all, determinations under Section **102(f)** involve the question of whether one party derived an invention from another"); *Price v. Symsek*, 988 F.2d 1187, 1190, 26 USPQ2d 1031, 1033 (Fed. Cir. 1993) (Although derivation and priority of invention both focus on inventorship, derivation addresses originality, i.e., who invented the subject matter, whereas priority focuses on which party invented the subject matter first.).

#### II. < PRIORITY TIME CHARTS

The following priority time charts illustrate the award of invention priority in several situations. The time charts apply to interference proceedings and are also applicable to declarations or affidavits filed under 37 CFR 1.131 to antedate references which are available as prior art under 35 U.S.C. 102(a) or 102(e). Note, however, in the context of 37 CFR 1.131, an applicant does not have to show that the invention was not abandoned, suppressed, or concealed from the time of an actual reduction to practice to a constructive reduction to practice because the length of time taken to file a patent application after an actual reduction to practice is generally of no consequence except in an interference proceeding. *Paulik v. Rizkalla*, 760 F.2d 1270, 226 USPQ 224 (Fed. Cir. 1985). See the discussion of abandonment, suppression, and concealment in MPEP § 2138.03.

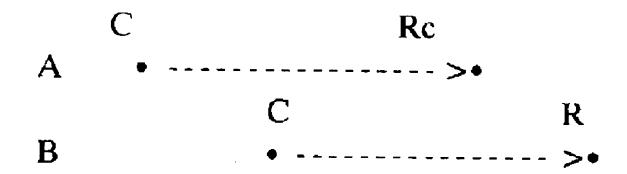
For purposes of analysis under 37 CFR 1.131, the conception and reduction to practice of the reference to be antedated are both considered to be on the effective filing date of domestic patent or foreign patent or the date of printed publication.

In the charts, C = conception, R = reduction to practice (either actual or constructive), Ra = actual reduction to practice, Rc = constructive reduction to practice, and T

D

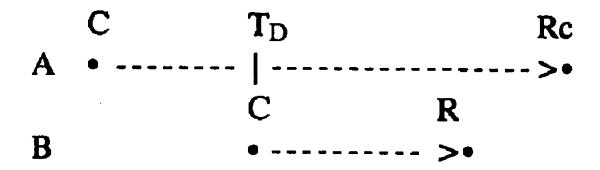
= commencement of diligence.

#### Example 1



A is awarded priority in an interference, or antedates B as a reference in the context of a declaration or affidavit filed under 37 CFR 1.131, because A conceived the invention before B and constructively reduced the invention to practice before B reduced the invention to practice. The same result would be reached if the conception date was the same for both inventors A and B.

#### Example 2

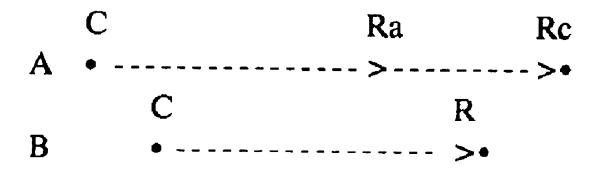


A is awarded priority in an interference, or antedates B as a reference in the context of a declaration or affidavit filed under 37 CFR 1.131, if A can show reasonable diligence from T

D

(a point just prior to B's conception) until Rc because A conceived the invention before B, and diligently constructively reduced the invention to practice even though this was after B reduced the invention to practice.

#### Example 3



A is awarded priority in an interference in the absence of abandonment, suppression, or concealment from Ra to Rc, because A conceived the invention before B, actually reduced the invention to practice before B reduced the invention to practice, and did not abandon, suppress, or conceal the invention after actually reducing the invention to practice and before constructively reducing the invention to practice.

A antedates B as a reference in the context of a declaration or affidavit filed under 37 CFR 1.131 because A conceived the invention before B and actually reduced the invention to practice before B reduced the invention to practice.

#### Example 4

A is awarded priority in an interference if A can show reasonable diligence from T

D

(a point just prior to B's conception) until Ra in the absence of abandonment, suppression, or concealment from Ra to Rc, because A conceived the invention before B, diligently actually reduced the invention to practice (after B reduced the invention to practice), and did not abandon, suppress, or conceal the invention after actually reducing the invention to practice and before constructively reducing the invention to practice.

A antedates B as a reference in the context of a declaration or affidavit filed under 37 CFR 1.131 because A conceived the invention before B, and diligently actually reduced the invention to practice, even though this was after B reduced the invention to practice.

>

#### III. < 37 CFR 1.131 DOES NOT APPLY IN INTERFERENCE PROCEEDINGS

Interference practice operates to the exclusion of *ex parte* practice under **37 CFR 1.131** which permits an applicant to show an actual date of invention prior to the effective date of a patent or literature reference applied under **35 U.S.C. 102(a)** or (e), as long as the patent is not a domestic patent claiming the same patentable invention. *Ex parte Standish*, 10 USPQ2d 1454, 1457 (Bd. Pat. App. & Inter. 1988) (An application claim to the "same patentable invention" claimed in a domestic patent requires interference rather than an affidavit under **37 CFR 1.131** to antedate the patent. The term "same patentable invention" encompasses a claim that is either anticipated by or obvious in view of the subject matter recited in the patent claim.). Subject matter which is available as prior art only under **35 U.S.C. 102(g)** is by definition made before the applicant made his invention and is therefore not open to further inquiry under **37 CFR 1.131**.

>

## IV. < LOST COUNTS IN AN INTERFERENCE ARE NOT, PER SE, STATUTORY PRIOR ART

Loss of an interference count alone does not make its subject matter <u>statutory</u> prior art to losing party; however, lost count subject matter that is available as prior art under **35 U.S.C. 102** may be used alone or in combination with other references under **35 U.S.C. 103**. But see *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992) (Under the principles of *res judicata* and *collateral estoppel*, Deckler was not entitled to claims that were patentably indistinguishable from the claim lost in interference even though the subject matter of the lost count was not available for use in an obviousness rejection under **35 U.S.C. 103**.).

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# Fritsch v. Lin (BdPatApp&Int) 21 USPQ2d 1731

# Fritsch v. Lin

U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences 21 USPQ2d 1731

> Decided December 3, 1991 Interference No. 102,096

## Headnotes

#### **PATENTS**

1. Practice and procedure in Patent and Trademark Office -- Board of Patent Appeals and Interferences -- In general (§ 110.1101)

## JUDICIAL PRACTICE AND PROCEDURE

# Procedure -- Prior adjudication -- Res judicata; collateral estoppel (§ 410.1503)

Board of Patent Appeals and Interferences must give due deference to deliberations and conclusions of the U.S. Court of Appeals for the Federal Circuit, and therefore board, in considering issues in interference which have already been considered by Federal Circuit on appeal of infringement suit involving same subject matter, must adopt findings of Copyright 2005, The Bureau of National Affairs, Inc. Reproduction or redistribution, in whole or in part, and in any form, without express written permission, is prohibited except as permitted by the BNA Copyright Policy. http://www.bna.com/corp/index.html#V

appellate tribunal on those issues if factual basis on which findings rest has not been undermined by new evidence.

#### **PATENTS**

2. Patentability/Validity -- Date of invention -- Conception (§ 115.0403)

Patentability/Validity -- Date of invention -- Reduction to practice (§ 115.0405)

## JUDICIAL PRACTICE AND PROCEDURE

# Procedure -- Prior adjudication -- Res judicata; collateral estoppel (§ 410.1503)

Junior party in interference has failed to establish conception of invention at issue prior to senior party's reduction to practice, since federal district court concluded in infringement suit that knowledge of appropriate erythropoietin amino acid sequence is necessary for complete conception of subject invention, since court further concluded that doctrine of simultaneous conception and reduction to practice is applicable in view of state of technology involved, since court's findings were affirmed on appeal, and since junior party has presented no additional evidence, not before district court, which directly contradicts or outweighs evidence supporting courts' conclusions.

#### **PATENTS**

3. Patentability/Validity -- Specification -- Best mode (§ 115.1107)

## JUDICIAL PRACTICE AND PROCEDURE

# Procedure -- Prior adjudication -- Res judicata; collateral estoppel (§ 410.1503)

Junior party in interference has not shown that senior party, by failing to deposit preferred cell strain for expressing erythropoietin gene, concealed best mode for practicing invention relating to purified and isolated DNA sequences encoding human EPO, since host cells are created by inserting genetic material into cells obtained from generally available sources, and thus description of best mode, and adequate description of means for carrying out invention, are sufficient to satisfy best mode disclosure

requirement without deposit of cells, since federal district court, in decision affirmed by U.S. Court of Appeals for the Federal Circuit, concluded that patent described preferred host cell strain in sufficient detail to allow one skilled in art to produce line of cells with satisfactory levels of EPO production, and since junior party has presented no additional evidence which directly contradicts or outweighs evidence considered by courts in reaching that conclusion.

#### **PATENTS**

4. Patentability/Validity -- Obviousness -- Relevant prior art -- Particular inventions (§ 115.0903.03)

#### JUDICIAL PRACTICE AND PROCEDURE

## Procedure -- Prior adjudication -- Res judicata; collateral estoppel (§ 410.1503)

Junior party in interference has not shown senior party's patent for DNA sequences encoding human erythropoietin to be obvious in view of probing technique disclosed in prior patent, since federal district court, in decision affirmed by U.S. Court of Appeals for the Federal Circuit, concluded that senior party's invention was not obvious, and since reference patent was before district court and thus, by implication, before Federal Circuit.

#### **PATENTS**

# 5. Patentability/Validity -- Inventorship (§ 115.13)

Motion of junior party in interference to delete two inventors named in patent application is denied, since standards for determining joint inventorship under 35 USC 116 are fairly broad in scope, since knowledge of correct erythropoietin amino acid sequence and precise procedures for isolating EPO gene, which two inventors are said to have contributed, are critical to conception of subject invention relating to purified and isolated DNA sequences encoding human EPO, and since junior party has not made factual presentation explaining in detail why such contributions should not be considered inventive.

# Particular patents -- Chemical -- DNA sequences

4,703,008, Lin, DNA sequences encoding erythropoietin, inventor held entitled to claims 1, 2, 4-6, 11-22, 28, and 31 corresponding to count in interference proceeding no. 102,096.

# Case History and Disposition:

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Patent interference between junior party Edward Fritsch, Rodney M. Hewick, and Kenneth Jacobs, application serial no. 06/693,258, filed Jan. 22, 1985, accorded benefit of serial no. 06/688,622, filed Jan. 3, 1985 and abandoned, and senior party Fu-Kuen Lin, patent no. 4,703,008, issued Oct. 27, 1987 on application serial no. 06/675,298, from continuation in part of serial no. 06/561,024, filed Dec. 13, 1983 and abandoned, serial no. 06/582,185, filed February 21, 1984 and abandoned, and serial no. 06/655,841, filed Sept. 28, 1984. Subject matter of count awarded to senior party Lin.

Related decision: 18 USPQ2d 1016.

## Attorneys:

Kurt E. Richter, Eugene Moroz, and William S. Feiler, New York, N.Y.; George A. Skoler, Purchase, N.Y.; Bruce M. Eisen, David L. Berstein, and Ellen J. Kapinos, Cambridge, Mass., for Fritsch, et al.

Paul N. Kokulis, Watson T. Scott, and Mary Jay Wilson, of Cushman, Darby & Cushman, Washington, D.C.; Michael F. Borun, Chicago, Ill.; and Steven M. Odre, Thousand Oaks, Calif., for Lin.

# Judge:

Before Serota, chairman, and R. Smith and Caroff, examiners-in-chief.

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# **Opinion Text**

# **Opinion By:**

Caroff, examiner-in-chief.

This interference involves an application of the junior party, Fritsch et al (Fritsch), and

a patent of the senior party, Lin. The Fritsch application is assigned to Genetics Institute, Inc. (GI) and the Lin patent is assigned to Amgen, Inc. (Amgen).

The subject matter in issue relates to a purified and isolated DNA sequence encoding for human erythropoietin (EPO), a protein consisting of 165 amino acids which is naturally produced in the body and which stimulates the production of red blood cells. Cf. Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 USPQ2d 1016, 1018 (Fed. Cir. 1991) (hereinafter referred to as the "Federal Circuit decision"). The sole count involved in this interference defines the subject matter at issue as follows:

Count I

A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

The claims of the parties which correspond to this count are:

Fritsch: Claims 1-8, 10, 13, 14, 16, 19, 22, 25, 26, 46, 48, 50, 52, 57, 58, 60, 62, 68-70 and 74

Lin: Claims 1, 2, 4-8, 11-29 and 31

#### Issues

The following issues are before us for adjudication:

- 1. Whether the Lin motion for judgment (Paper No. 123) which is based upon the aforementioned Federal Circuit decision should be granted.1
- 2. Whether Fritsch has adduced sufficient evidence to establish prior inventorship with respect to the subject matter defined by the count.
- 3. Whether Fritsch has adduced sufficient evidence to establish that Lin has failed to satisfy the "best mode" requirement of 35 USC 112.2
- 4. Whether Lin's involved claims are unpatentable to Lin under 35 USC 103. 3
- 5. Whether the Fritsch motion to correct inventorship (Paper No. 54), and companion motion for leave to file a corrected preliminary statement (Paper No. 52), should be granted.4
- 6. Whether the motion by Lin under 37 CFR 1.635 and 1.656(h) to suppress evidence (Paper No. 141) should be granted.
- 7. Whether the motion by Fritsch under 37 CFR 1.635 and 1.656(h) to suppress evidence (Paper No. 136/137) should be granted.

Both parties took testimony, submitted exhibits, and filed briefs. In addition, Lin submitted documents under Section 1.682 (Paper No. 127) and Fritsch submitted proposed findings of fact and conclusions of law (Paper No. 135). 5 No issue of interference-in-fact is before us.

- 1. The Lin Motion for Judgment
- [1] The fundamental question raised in the subject motion is whether the Federal Circuit decision is binding upon us as to issues 2 (priority), 3 (best mode) and 4 (obviousness) above. 6 For the reasons discussed below, the motion is *granted* to the extent that we shall follow and adopt the principles and findings set out in the Federal Circuit decision insofar as Fritsch has failed to present any new evidence, not before the court, which directly contradicts and outweighs the evidence before the court. In other words, we are bound by the Federal Circuit decision to the extent of the evidence considered by the court, *viz*., to the extent the record is the same, we are compelled to reach the same conclusions.

None of the case law cited by either party in this interference appears to be especially applicable to the situation at hand. Evidently, this is a case of first impression where we are asked in an interference proceeding to reconsider questions which have already been decided by a district court, and where the decision of the district court has been

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affirmed on appeal to the Federal Circuit, our own appellate tribunal. In particular, none of the cases cited by Fritsch appear to involve a refusal by the Board in an interference proceeding to be bound by a final decision 7 of our reviewing court, albeit a decision affirming the holdings of a district court. In fact, decisions and legal principles enunciated by our reviewing court, now the Court of Appeals for the Federal Circuit, are binding and controlling on the Board. *Cf.*, Rivise and Caesar, *Interference Law and Practice*, Vol. IV. Section 784, p. 2780 (Michie Co. 1948). Accordingly, in this case we must give due deference to the deliberations and conclusions of our appellate tribunal if the factual basis on which they rest has not been undermined by new evidence.

2. Fritsch's Case for Priority

Fritsch conceded at final hearing that the invention at issue was successfully reduced to practice by Lin in October 1983 and thereafter by Fritsch. (PF II-343). In other words, Fritsch concedes that Lin actually reduced the subject invention to practice before Fritsch. Accordingly, in order to prevail on the issue of prior inventorship, Fritsch, as the last to reduce to practice, must establish that he was the first to conceive and proceeded with reasonable diligence to reduce the subject invention to practice from a time prior to conception by Lin. 35 USC 102(g).

The evidence adduced by Fritsch establishes the following chronology of activities which inure to the benefit of Fritsch and GI. In December 1981, Fritsch envisioned a strategy for isolating the EPO gene which would involve using two sets of fully degenerate probes to screen a genomic DNA library. (PF II-8; FR 6546-47 (Maniatis)). This strategy was employed in 1982 and 1983 and resulted in a number of unsuccessful initial screenings (PF II-63 through II-86). By May 1983, Fritsch concluded that the initial screenings were unsuccessful because of a suspected error in the EPO amino acid sequence data which he had obtained from Dr. Hewick of GI and upon which he had relied to design complementary oligonucleotide probes. (PF II-86). It was later determined that the sequence data was indeed incorrect (FB-9; PF II-56, II-57). Accordingly, GI sought to obtain additional purified urinary EPO in order to derive more accurate EPO sequence information. These efforts were initially unsuccessful. Ultimately, in April 1984, GI purportedly obtained some purified EPO from a Dr. Miyake. The EPO was then used by Dr. Hewick to obtain new amino acid sequence data (PF II-105). Within about two months of obtaining the correct sequence information, Fritsch successfully obtained the EPO gene by employing his cloning strategy (PF II-105 through II-113).

Essentially the same set of facts was before the Federal Circuit. Based upon the record before it, the court agreed with the findings of the trial court 8 that, at the time in question, conception of a process for cloning the EPO gene was incomplete absent adequate knowledge of the structure of EPO or the EPO gene itself and, in view of the uncertainties of the envisioned cloning strategy and the lack of information concerning

the amino acid sequence of EPO, neither party had an adequate conception of the DNA sequence until reduction to practice had been achieved.

- [2] We find no explicit reference by Fritsch in his opposition to Lin's motion for judgment, or in any of his briefs or at final hearing, to any new evidence, not before the court, which directly contradicts and outweighs the evidence which led the court to conclude that knowledge of an appropriate EPO amino acid sequence is necessary for a complete conception of the subject invention and that the doctrine of simultaneous conception and reduction to practice is applicable in view of the state of technology involved. By way of example, we note that PF III-33, which is specifically relied on by Fritsch (FB-21), is based on the record before the trial court and not based on any new evidence. Therefore, we find no reason under any appropriate standard of proof to reach a conclusion different than that reached by the courts in which the issue of priority has already been litigated. Accordingly, we hold that Fritsch has failed to establish an adequate conception of the invention at issue prior to Lin's reduction to practice.

  3. The Question of "Best Mode"
- [3] With respect to the issue of "best mode", Fritsch argues that Lin concealed the best mode of carrying out his invention by failing to deposit his preferred cell strain (CHO B11, 3.1) for expressing the EPO gene. Fritsch relies upon statements by the district court to the effect that the testimony

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is clear that no scientist could ever duplicate exactly the best mode host calls used by Amgen. However, as pointed out by Lin, both the district court and the Federal Circuit also determined in the Amgen v. Chugai litigation that the best mode of practicing the subject invention, including the preferred host cell strain, was described in sufficient detail in Example 10 of the involved Lin patent to apprise those of ordinary skill in the art how to produce mammalian host cell strains or lines with levels of EPO production similar to those identified in Example 10. In other words, it has been determined that "the invention, as it relates to the best mode host cells, could be practiced by one skilled in the art following Example 10" and, therefore, a deposit is not required.

As explained more fully in the Federal Circuit decision (18 USPQ2d at 1025):

These materials are therefore not analogous to the biological cells obtained from unique soil samples. When a biological sample required for the practice of an invention is obtained from nature, the invention may be incapable of being practiced without access to that organism. Hence the deposit is required in that case. On the other hand, when, as is the case here, the organism is created by insertion of genetic material into a cell obtained from generally available sources, then all that is required is a description of the best mode and an adequate description of the means of carrying out the invention, not deposit of the cells. If the cells can be prepared without undue experimentation from known materials, based on the description in the patent specification, a deposit is not required. See Feldman v. Auntstrup, 517 F.2d 1351, 1354, 186 USPQ 108, 111 (CCPA 1975), ("No problem exists when the microorganisms used are known and readily available to the public."), cert. denied, 424 U.S. 912 [188 USPQ 720] (1976). Since the court found that that is the case here, we therefore hold that there is no failure to comply

with the best mode requirement for lack of a deposit of the CHO cells when the *best mode* of preparing the cells has been disclosed and the best mode cells have been enabled, *i.e.*, they can be prepared by one skilled in the art from known materials using the description in the specification.

The court also indicated that the best mode requirement does not mandate a disclosure sufficient to enable exact duplication of the inventor's best mode. What is required, according to the Federal Circuit decision, is an adequate disclosure of the best mode and not a guarantee that every aspect of the specification be precisely and universally reproducible.

Based upon the foregoing findings, the "best mode" issue was decided in favor of Lin. We find no new evidence relied upon by Fritsch which directly contradicts and outweighs the evidence relied upon by the courts in reaching their findings concerning Lin's satisfaction of the "best mode" requirement. Therefore, we find no reason under any appropriate standard of proof to disturb those findings and, accordingly, hold that the Lin disclosure is sufficient to satisfy the "best mode" requirement of 35 USC 112.

4. The Issue of "Obviousness"

According to the Federal Circuit and district court decisions, at the time of Lin's invention a person of ordinary skill in the field of gene cloning, armed with the knowledge available in the prior art, would have found it "obvious to try" to isolate the EPO gene using the probing technique employed by Lin but, in view of a difference of opinion among the experts, the evidence was found to be insufficient to establish that there was a "reasonable expectation of success" in cloning the EPO gene based on the probing strategy disclosed in the prior art.

[4] To establish the obviousness of Lin's involved claims in this interference, Fritsch principally relies upon the Toole et al reference (U.S. Patent No. 4,757,006, FX-34) as prior art. However, according to Lin (Paper No. 123, page 7), the Toole et al reference was before the district court and thus, by implication, also before the Federal Circuit. This is not disputed by Fritsch. Thus, there appears to be no evidence before us which was not considered in the preceding litigation and, therefore, we find no basis for reaching a different conclusion on the question of "obviousness". Accordingly, we hold that the subject matter of Lin's involved claims would not have been obvious within the context of 35 USC 103.

With respect to the Toole et al reference, it is instructive to repeat some of the remarks of the Examiner-in-Chief in his Decision on Motions (Paper No. 33) as to "Motion E" which we find to be pertinent with respect to the question of "obviousness" as well as the issues raised in Motion E. To wit, it was pointed out that the "earlier applications" of Fritsch's assignee, i.e., the Toole et al reference, do not specifically mention EPO and refer only to the production of a different protein, "Factor VIII:C". Further, the following averment by Fritsch was said to contradict any assertion that the cloning technique of Toole et al is generally applicable:

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One cannot identify clearly all of the genes for which this cloning approach is

applicable, however, it is quite clear that the numbers are quite small and constitute a readily identifiable class of materials.

It should be clear that the aforementioned statement, made under oath, suggests that the enabling scope of the Toole et al disclosure is limited with respect to the cloning of genes other than the factor VIII:C gene. In this regard, the Toole et al disclosure does not appear to provide any more guidance for cloning an EPO gene than the other prior art references which were considered in the preceding litigation.

## 5. The Fritsch Motion to Correct Inventorship

For the reasons discussed below, the subject motion shall be *denied*. While the motion may be considered moot in view of our determination of the issue of prior inventorship, we shall consider the motion on its merits for the sake of completeness. We note that the companion motion for leave to file a corrected preliminary statement involves the same questions raised in the motion at issue and, therefore, shall also be *denied*.

The party Fritsch argues that Hewick and Jacobs should be deleted as co-inventors since they were originally named as inventors under the mistaken belief that inventors are identified on the basis of the same standards by which coauthors of scientific papers are identified. (PF VII-11,12).

According to the verified statements of the inventors and their attorney Skoler (FR 4196-4208), Hewick's scientific contribution included providing EPO amino acid sequence data and Jacobs' included procedures used in screening a genomic library and isolating the EPO gene. The statements indicate that the "error" in naming Hewick and Jacobs as inventors arose by reliance on their "scientific contributions" that did not meet the standard for "inventive contribution". However, the statements do not specifically indicate and explain the factual basis for the present belief that Hewick's and Jacobs' scientific contributions do not amount to inventive contributions.

Lin argues that the verified statements are essentially conclusory, at best, with no detailed explanation of how the alleged "error" occurred. Lin also asserts that the attempt to correct inventorship was not "diligently made" as required by 37 CFR 1.48(a) since there is no indication why the "error" was not discovered earlier when Fritsch was preparing its Section 1.608(b) showing or its preliminary statement. In this regard, it is noted that the purported error is said by Fritsch to have been first discovered at a meeting held on September 10, 1990, yet Fritsch does not specifically deny the charge that Fritsch's trial counsel in the Boston infringement litigation argued as early as April 1989, over a year earlier, that Fritsch was the sole inventor of the subject matter defined by the count at issue here.

[5] We entirely agree with Lin that the motion to correct inventorship should be denied for the reasons stated by Lin. For emphasis, we observe that Fritsch has established no factual basis to support its conclusion that the scientific contributions of Hewick and Jacobs do not amount to inventive contributions. The fact that an overly broad standard was initially applied to identify the inventors at GI does not necessarily establish that an error was committed which actually resulted in an incorrect designation of inventors. In this regard, we note that the standards for determining joint inventorship are also fairly broad in scope -- see 35 USC 116.

We are aware that the statute governing inventorship conversion is remedial in nature and, therefore, is ordinarily liberally construed. However, in this case it has been determined in considering the question of prior inventorship that knowledge of correct

EPO amino acid sequence information and precise procedures for isolating the EPO gene are critical aspects of conception with respect to the invention at issue. These are the very components of the invention to which Hewick and Jacobs are said to have contributed. Therefore, in our opinion, it was incumbent upon Fritsch to make a factual presentation and explain in detail why the contributions of Hewick and Jacobs should not be considered inventive. This Fritsch has failed to do.

## 6. The Lin Motion to Suppress

We do not reach the subject motion for decision. We find it unnecessary to consider the specific objections raised in the motion since we have found that Fritsch does not prevail on any substantive issue before us even after having considered all of Fritsch's evidence of record in its entirety. Therefore, there is no need to consider whether some of that evidence is admissible or not. In this regard, Lin himself recognizes in his motion (page 2) that it may not be necessary to consider the objections. Additionally, we observe that many of Lin's objections, and virtually all of those pertaining to Fritsch's proposed findings, go to the weight of the evidence rather than its admissibility.

### 7. The Fritsch Motion to Suppress

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We find it unnecessary to consider the specific objections raised by Fritsch since, as should be apparent, none of our substantive determinations in this interference are based upon those portions of the record and exhibits to which Fritsch objects. Therefore, although we have considered all of the evidence introduced by the parties, in reaching our conclusions we gave no weight to the evidence which is objected to by Fritsch.

# Judgment

For the foregoing reasons, judgment as to the subject matter of the count in issue is hereby awarded to Lin, the senior party.

Accordingly, Fu-Kuen Lin is entitled to his patent containing claims 1, 2, 4-6, 11-22, 28, 31 corresponding to the count. 9 Edward Fritsch, Rodney M. Hewick and Kenneth Jacobs, the junior party, are not entitled to a patent containing claims 1-8, 10, 13, 14, 16, 19, 22, 25, 26, 46, 48, 50, 52, 57, 58, 60, 62, 68-70, 74 corresponding to the count.

#### **Footnotes**

Footnote 1. Consideration of the Lin motion for judgment and of the Fritsch opposition thereto (Paper No. 122) was deferred to final hearing in Paper No. 132.

Footnote 2. The "best mode" issue was originally raised by Fritsch in a preliminary motion (Motion B) and was deferred to final hearing in Paper No. 33.

Footnote 3. The issue of "obviousness" under 35 USC 103 was originally raised by

Footnote 3. The issue of "obviousness" under 35 USC 103 was originally raised by Fritsch in a preliminary motion (Motion A) and was deferred to final hearing in Paper No. 33.

Footnote 4. Consideration of the indicated motions, as well as associated oppositions and replies, was deferred to final hearing in Paper No. 56.

Footnote 5. The Fritsch testimony record, exhibits, brief, reply brief and proposed findings will hereinafter be respectively referred to as "FR", "FX", "FB", "FRB" and "PF" followed by an appropriate page or exhibit number. The Lin testimony, exhibits and brief will be similarly referred to as "LR", "LX" and "LB".

Footnote 6. The Federal Circuit decision, like the present interference, relates to Lin patent 4,703,008. In fact, claim 2 of the patent is identical to the count at issue in the interference.

Footnote 7. We note that the Federal Circuit decision of interest here is now final (Paper Nos. 124, 126, 151).

Footnote 8. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 USPQ2d 1737 (D.Mass. 1990). We note here that Chugai Pharmaceutical Co. (Chugai) is a licensee of GI, the assignee of junior party Fritsch.

Footnote 9. We note that Lin's remaining claims corresponding to the count, i.e., claims 7, 8, 23-27, 29, were held to be invalid under 35 USC 112 in the Federal Circuit decision for lack of enablement.

- End of Case -

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